

**Psychological Correlates of Long-Term
Benzodiazepine Use in a Primary Care Population**

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I hereby declare that this thesis has been composed by myself and the work contained herein my own.

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Abstract

Objectives

Long-term use of benzodiazepine medication results in dependence, tolerance, withdrawal symptomatology, and reduced pharmacological efficacy. In addition, long-term use of benzodiazepines can have adverse effects on cognitive, psychomotor and psychological functioning. In response to these problems prescribing guidelines clearly discourage the long-term use of benzodiazepines.

The aim of the study was to examine the long-term use of benzodiazepine medication in a primary care population. The study included patients who were prescribed benzodiazepines by their general practitioners for sleep problems. Detailed information was collected regarding psychopathology, sleep difficulties and benzodiazepine dependence in this patient group with the aim of establishing whether a common psychological profile prevailed amongst those individuals who had been taking prescribed benzodiazepine medication for longer than the recommended period of time.

This research study could therefore offer support to general practitioners by providing a greater psychological understanding of this client group, and this knowledge could inform alternative treatment options.

Design

The research design employed was a cross-sectional survey of an identified population using standardised questionnaires. The design therefore utilised between subject measures to examine the relationships between subjects on a number of variables.

Method

Eighty-four participants, recruited from two rural primary care practices, took part in the study. Data were collected using a semi-structured interview and administration of four self-report questionnaire measures (The Pittsburgh Sleep Quality Index; The Brief Symptom Inventory; The Severity of Dependence Scale; The Psychological Mindedness Scale).

Results

Results found significant psychopathology (somatisation and phobic anxiety) in long-term benzodiazepine users. Anxiety was found to significantly predict benzodiazepine dependence and sleep difficulties. The use of long-term benzodiazepine medication did not relieve sleep difficulties. Older benzodiazepine users and daily benzodiazepine users were significantly less psychologically minded than younger users and non-daily users.

Conclusion

The study concluded that long-term benzodiazepine use is ineffective in treating sleep difficulties and it would appear that anxiety is a significant feature in this cohort. Therefore, the study proposes that to address the problem of long-term benzodiazepine use in the primary care setting, psychological approaches should be employed to treat anxiety and sleep difficulties.

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Chapter 1: The Benzodiazepines

What are benzodiazepines?

Benzodiazepine is the name given to a sub-group of drugs, that sit within the larger classification of psychotropic drugs. Benzodiazepines are referred to as minor tranquillisers.

Whilst most people are unfamiliar with the word benzodiazepine, with the exception of illicit drug users who refer to benzodiazepines as “benzos”, the general public are familiar with the word “tranquilliser”. Taken from the adjective “tranquil” which means “Serene, free from agitation or disturbance” (Concise Oxford Dictionary), “a tranquilliser” is a sedative drug.

The pursuit and use of compounds to relieve anxiety stretches back thousands of years, for example the discovery of alcohol some 8000 years ago is well documented, along with the use of opium and other naturally occurring drugs across other cultures. However, it was not until the nineteenth century, following the Industrial Revolution and the subsequent growth of chemical knowledge and manufacturing, that the development of pharmaceutical remedies gave rise to the production of synthetic compounds which could be used for sedation.

At the turn of the twentieth century the most widely used synthetic drugs for sedation were the barbiturates. First developed in 1903, the popularity of barbiturates steadily rose until the 1950s when it levelled off. By the 1970s the abuse and dependence-inducing properties of these compounds had been well publicised and prescribing doctors were strongly encouraged to replace the barbiturates with benzodiazepines. In addition, the barbiturates were found to have a lower degree of selectivity, increased CNS suppression, cause more drug interaction and were found to be more lethal in overdose than benzodiazepines.

The development of the benzodiazepines began in Poland in the mid-1930's, but not until 1957 were the benzodiazepines clearly established as having hypnotic and sedative effects

(Sternbach 1980). The first benzodiazepine to be introduced on to the market was chlordiazepoxide (Librium) in 1960, closely followed by its more successful associate, diazepam (Valium) in 1963.

What are benzodiazepines used for and how do they work?

Following four decades of use, benzodiazepines remain one of the most widely prescribed drugs. Their role has been expanded from their original use in the treatment of anxiety and sleep disorders, for use with epilepsy, anaesthesia, some motor disorders and occasionally in acute psychosis and mania. Nevertheless, despite these additional uses for benzodiazepines a sizeable majority of patients still receive their prescription for sleep and anxiety problems. Benzodiazepines used for their sleep-inducing properties are classed as hypnotics and those used to reduce anxiety are classed as anxiolytics.

The main effect of benzodiazepines is that of increasing the activity of the neurotransmitter GABA (gamma-aminobutyric acid). GABA exerts an inhibitory effect by reducing the sensitivity of neurons with the result that it takes more to excite them. It is thought that a deficiency of GABA may explain overarousal, a key feature of anxiety. Therefore, raising GABA levels or enhancing its effect should reduce anxiety. At the cell membrane level, benzodiazepines bind to a receptor site on a GABA receptor and enhance the effect of GABA, with the result that the GABA chloride channel opens more often, releasing chloride ions that hyperpolarize the cell, making it less likely to fire.

The range of indications and the relative effectiveness of benzodiazepines (certainly in the short-term) have contributed to their popularity and wide-spread use. In general, benzodiazepines are well tolerated and their main “apparent” side-effect is one of drowsiness and sedation, this compares more favourably with many other regularly prescribed medications in general medicine. However, after many years of usage, and a significant

amount of published research, benzodiazepines are now known to cause a wide range of adverse effects, particularly with long-term use. As evidence materialised supporting both acute and chronic side-effects as well as toxicity, changes were made to the guidelines regarding benzodiazepine prescribing.

There are approximately 50 benzodiazepine derivatives available for clinical use, although of these only around a dozen are in regular use. Differences between different benzodiazepines are relatively small but can be clinically significant. In clinical practice it is not uncommon to encounter patients who report that the efficacy of a particular benzodiazepine is not matched when they are transferred to a different one. However, it has been argued that this specificity of action is likely to be psychologically based (Tyrer 1991). Research has shown that when patients were changed to another benzodiazepine (equivalent doses) under double-blind conditions there was no difference between the withdrawal symptoms of those patients that had changed benzodiazepine and the group that had remained on the same one (Murphy and Tyrer 1991). Nevertheless, this finding concerns withdrawal symptoms, not variations in potency effects or onset of action.

Differences between benzodiazepines: Half-life, duration of action and potency

Benzodiazepines are usually classified according to their beta elimination half-life. Beta half-life is defined as “the rate of decline due to drug elimination through metabolism to inactive conjugated forms and excretion” (p.70 Nelson and Chouinard 1999). Benzodiazepines that are more rapidly cleared from the body are labelled as having a “short half-life” and those with a longer rate of elimination are referred to as having a “long half-life”. Elimination half-life varies considerably from 2 to 100 hours. Estimates for three benzodiazepines are given below (Table 1). In addition, some benzodiazepines have pharmacologically active metabolites that may produce cumulative effects (Aston 1994). Cumulative effects are an important consideration when prescribing benzodiazepines

particularly for older patients. Conversely, short-acting benzodiazepines with no metabolites are more likely to give rise to withdrawal or rebound symptoms if doses are missed because the drug leaves the body more rapidly.

Table 1: Half-life of three benzodiazepines

Hypnotics	Anxiolytics	Elimination half-life (hours)	Half-life of pharmacologically active metabolite (hours)
Nitrazepam		15–38	
Temazepam		8–15	
	Diazepam	20–100	36–200

(Source: p 27, Aston 1994)

Duration of action is another feature used to distinguish between different benzodiazepines. Duration of action is not the same as elimination half-life; it is dependent on rate of absorption, uptake in to the central nervous system and binding at the benzodiazepine GABA receptor. Benzodiazepines will rapidly enter brain tissue once in the circulatory system, therefore the onset of action is most closely related to absorption from the gastrointestinal tract. Benzodiazepines that are absorbed more quickly include diazepam, which therefore has a rapid onset of action and may sometimes produce more euphoria as a result.

Potency and half-life are not related. Potency refers to the receptor binding affinity of a benzodiazepine, for example alprazolam (high potency) binds with greater affinity and is therefore more potent than diazepam (medium potency); temazepam is an example of a benzodiazepine that has a low potency.

Physiological dependence: tolerance and withdrawal

Addiction is understood in terms of both psychological and physiological dependence. Tolerance and withdrawal mediate physiological dependence. Different benzodiazepines present with different risks of physiological dependence. This is because the risk is related to factors such as long half-life, low clearance and cumulative drug load. Also, physiological dependence implies a biological adaptation to the effects of the drug: this is referred to as tolerance. Tolerance is explained in terms of the reduced efficacy of a drug with repeated use, resulting in higher doses being required to achieve the same effect. Tolerance depends on altered receptor function or a change in the numbers of receptors and is commonly referred to as receptor adaptation. Tolerance can develop over several days or weeks and is usually associated with hypnotics rather than anxiolytics.

Discontinuation of benzodiazepines can produce three types of symptoms: recurrence (a return of the original symptoms), rebound (return of the original symptoms but more intensely experienced than original baseline level) and withdrawal (new symptoms that were not present in the original illness).

DIAGNOSTIC CRITERIA FOR 292.0 SEDATIVE, HYPNOTIC, OR ANXIOLYTIC WITHDRAWAL

A. Cessation of (or reduction in) sedative, hypnotic, or anxiolytic use that has been heavy and prolonged.

B. Two (or more) of the following, developing within several hours to a few days after criterion A:

- (1) Autonomic hyperactivity (e.g. sweating or pulse rate greater than 100)
- (2) Increased hand tremor
- (3) Insomnia
- (4) Nausea or vomiting
- (5) Transient visual, tactile, or auditory hallucinations or illusions
- (6) Psychomotor agitation
- (7) Anxiety
- (8) Grand mal seizures

C. The symptoms in criterion B cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.

Specify if: With Perceptual Disturbances.

From DSM-IV (1994) p 266.

COMMONLY OBSERVED WITHDRAWAL SYMPTOMS

Anxiety
Irritability
Insomnia
Fatigue
Headache
Muscle twitching or aching
Tremor, shakiness
Sweating
Dizziness
Concentration difficulties
*Nausea, loss of appetite
*Observable depression
*Depersonalization, derealization
*Increased sensory perception (smell, sight, taste, touch)
*Abnormal perception or sensation of movement

*Symptoms more likely to represent true withdrawal rather than an exacerbation or return of original anxiety.

p. 138, Roy-Byrne and Nutt (1991)

With abrupt discontinuation from benzodiazepine medication, symptoms can develop within 24 hours for the short and intermediate half-life drugs and within three to eight days with the longer-acting drugs. Even following a gradual taper regime, large numbers of users experience withdrawal symptoms. Schweizer et al (1990) found that more than 90% of long-term users (over 8–12 months) experienced withdrawal symptoms regardless of whether they withdrew slowly or rapidly. Noyes et al (1988) concluded from a review of studies that almost half of those that had taken benzodiazepines for more than three years experienced a withdrawal reaction when they stopped their medication. Nevertheless, the prevalence of withdrawal symptomatology following discontinuation of benzodiazepines is difficult to establish, as most studies have their own definition of what constitutes a withdrawal symptom.

The likelihood of a withdrawal reaction is mediated by the following factors (Miller 1997):

Drug factors:

- ◆ Short half-life
- ◆ High potency
- ◆ Abrupt discontinuation
- ◆ High dosage
- ◆ Chronic use

Patient factors:

- ◆ Traits of neuroticism
- ◆ Mild/moderate alcohol use
- ◆ Less well educated
- ◆ More panic/anxiety/depression at baseline
- ◆ Prior history of alcohol/drug abuse
- ◆ Self report “addicted”/“hooked”

Withdrawal symptoms can be minimised by transferring the patient to a slowly eliminated benzodiazepine (usually diazepam) and then gradually tapering the dose before discontinuing.

Psychological dependence

Historically, substance dependence has proved to be a difficult concept to define, and it has undergone many revisions. In recent decades the introduction of the distinction between physical and psychological dependence has caused both conceptual and operational difficulties. Currently, substance dependence is defined in terms of both physiological dependence and psychological dependence, neither being mutually exclusive. It would seem likely that this terminology was developed from the earlier distinction made by the World Health Organisation (1964) when the two terms “addiction” and “habituation” were used. Much of the literature has focused on dependence as a physical response because it is easier to establish than psychological dependence. It is argued that medical evidence in terms of “withdrawal symptoms” and “tolerance” is widely understood and provides a perceptible measure of physical dependence (Lader 1981).

However, focusing solely on physiological dependence does not satisfy those theorists that support the concept of psychological dependence as a state arising from the process of positive reinforcement, in contrast to negative reinforcement which underlies physiological dependence (Ray and Kair 1987). Psychological dependence is characterised by the reinforcing effects of a drug. The conceptualisation of drugs as reinforcers postulates that drug-using and drug-seeking behaviours are examples of operant behaviour maintained by their consequences. Reinforcing effects are found to correlate with drug self-ingestion (Roache 1990). Benzodiazepines with increased speed of onset, short half-life, high clearance and higher potency are said to have greater reinforcing effects and therefore have an increased (psychological) addiction potential. The much-reported “addictive” properties of the drug cocaine are explained in terms of psychological addiction because research has failed to establish that physical dependence occurs with repeated use.

The Diagnostic and Statistical Manual of Mental Disorders IV (DSM-IV, American Psychiatric Association 1994) describes substance dependence as follows:

“The essential feature of Substance Dependence is a cluster of cognitive, behavioural, and physiological symptoms indicating that the individual continues use of the substance despite significant substance-related problems. There is a pattern of repeated self-administration that usually results in tolerance, withdrawal and compulsive drug-taking behaviour.”

The manual then proceeds to define tolerance, withdrawal and compulsion, but claims because dependence can be present without tolerance or withdrawal (e.g. cannabis dependence) a further specification is required:

“The specifiers: With Physiological Dependence and Without Physiological Dependence, are provided to indicate the presence or absence of tolerance or withdrawal.” (DSM-IV, 1994).

The dependence potential of benzodiazepine medication was not taken seriously during the 1960s and 1970s. Marks (1978) examined a significant amount of published research from this period and concluded that the risk of dependence following benzodiazepine use was very low, a conclusion that was out of step with guidelines published by the CRM (1980). This document brought to attention to the potential to develop withdrawal symptoms even with short-term usage, with the result that stricter prescribing guidelines were introduced. An abundance of research followed during the 1980s, which demonstrated that not only was dependency a possibility following high-dose usage of benzodiazepine medication, but that therapeutic doses could also produce dependence. Withdrawal syndromes, regardless of whether an individual was withdrawing from high-dose misuse or low-dose use, were found to be the same (Hallstrom and Lader 1981).

Prevalence rates of benzodiazepine use

In the published literature there exists an abundance of reported prevalence rates for benzodiazepine use, of which many vary considerably. The following four studies are cited

because they were all concerned with prevalence rates in general practice populations and are relatively up-to-date.

Zandstra et al (2002) assessed the effects of employing various definitions of benzodiazepine use and various observation periods on the prevalence rate of benzodiazepine use, across 31 general practice populations in the Netherlands ($N = 80,315$). Prevalence rates varied between 2.2 per cent and 17.6 per cent. Among long-term benzodiazepine users approximately 80 per cent were older than 45 years.

Wilcock et al (1999) surveyed thirty-four Cornish general practices ($N = 172,278$) and found that 2.62 per cent of the population were in receipt of a repeat prescription for a hypnotic, with females more likely than males to be receiving hypnotic medication (3.45 per cent vs. 1.7 per cent). This study revealed that hypnotic prevalence is clearly associated with older age. Combining sex a repeat prescription rate of 4.61 per cent is reported in the 65 to 74-year-old group, 9.14 per cent in those aged 75–84 years, and 16.42 per cent for those aged over 85.

Escriva et al (2000) examined the prevalence of benzodiazepine use in a Spanish primary care sample ($N = 7356$) and found a prevalence rate of 7.7 percent; 42 per cent of these patients had been taking benzodiazepines for over 1 year.

A cross-sectional audit of general practice patients in Italy by Barburi et al (1998) assessed long-term benzodiazepine use. The study involved twenty-six general practitioners who provided details of all their patients that were taking benzodiazepines. The prevalence of benzodiazepine use was 14.0 per cent, while the prevalence of daily use for 12 months or more was 4.7 per cent.

Prescribing guidelines for benzodiazepines

In 1980, an article was published in the British Medical Journal that was to be frequently cited in future publications. The article was a report of a review carried out by the Committee on the Review of Medicines (CRM) and was titled “Systematic review of the benzodiazepines”. The significance of this particular review was in the guidelines it proposed for the data sheets on the most commonly used benzodiazepines. These new guidelines were based on an examination of the efficacy and safety of benzodiazepine drugs by the CRM. These guidelines drawn up over 20 years ago have remained virtually unchanged to date.

Efficacy

The CRM reported that “all benzodiazepines were efficacious in the short-term treatment of symptoms of anxiety and in insomnia” (p.910), although in terms of efficacy it stated that there was no evidence to support the use of one benzodiazepine in preference to another in the treatment of anxiety or insomnia. The committee also stated that benzodiazepines were “unsuitable” for the treatment of conditions such as depression or tension headaches because they had no antidepressant or analgesic properties.

The CRM stated that they were particularly concerned that there was a lack of evidence of efficacy to support the long-term use of benzodiazepines in the treatment of anxiety and insomnia. They cited evidence from a study carried out by the White House Office of Drug Policy and National Institute on Drug Abuse (1979), which found that sleep laboratory studies demonstrated that most hypnotics do not assist sleep following 3–14 days of continuous use. In addition, the CRM said that there was a lack of evidence that benzodiazepines continued to be efficacious in the treatment of anxiety after four months of continuous use.

Safety

The CRM reported that they were concerned about the high numbers of repeat prescriptions for benzodiazepines "in spite of the lack of satisfactory clinical studies establishing long-term efficacy" (p.911). They highlighted the problem of withdrawal symptoms and advised that benzodiazepine prescriptions be limited to short-term use, be withdrawn gradually and only be used at doses within the therapeutic range (whenever possible). The committee also drew attention to the problems of daytime sedation, the effect on reaction times and the potentially dangerous interaction with alcohol.

Finally, the CRM highlighted the potential for more serious reactions in the elderly, in particular, the slower elimination of benzodiazepines in elderly people, which has implications for the use of the longer-acting drugs for insomnia. The data sheets recommend that "half the normal adult dose may be sufficient for a therapeutic response in the elderly" (p.912).

In 1988 the Committee on Safety of Medicines added a further recommendation **that benzodiazepines should not be used for more than 4 weeks, and then at only the lowest possible dose to control symptoms**. Subsequently, The Department of Health (1992) and the British Medical Association (1993) have also discouraged the long-term use of benzodiazepines.

Current prescribing guidelines for diazepam, nitrazepam and temazepam

DIAZEPAM

Dose: *by mouth*, anxiety, 2 mg 3 times daily increased if necessary to 15–30 mg daily in divided doses; ELDERLY (or debilitated) half adult dose. Insomnia associated with anxiety, 5–15 mg at bedtime.

NITRAZEPAM

Dose: 5–10 mg at bedtime; ELDERLY (or debilitated) 2.5–5 mg.

TEMAZEPAM

Dose: 10–20 mg at bedtime, exceptional circumstances 30–40 mg; ELDERLY (or debilitated) 10 mg at bedtime, exceptional circumstances 20 mg.

(Source: British National Formulary 2002)

The adverse effects of benzodiazepines

Research has shown that benzodiazepine medication can have adverse effects on cognitive, psychomotor and psychological functioning (Lader 1999).

Cognitive effects

Benzodiazepines can cause memory problems. A number of studies have shown that following the administration of benzodiazepine medication the ability to learn new information is impaired. It is said that benzodiazepines disrupt the process of taking information from short-term stores into long-term memory storage (Curran 1991). Therefore, an individual given a dose of a benzodiazepine will be able to remember immediate information and information before the drug was taken, but they will have more difficulty remembering information given to them whilst the benzodiazepine is active in their system (anterograde memory). Dramatic effects are demonstrated when single doses are given to individuals who do not normally use benzodiazepines. However, reduced effects are also found in those individuals that receive repeated doses, suggesting that some tolerance to this effect does develop but that it is incomplete and will vary according to the individual (Lader 1999).

Anterograde amnesia is increased with increased dose, faster absorption and higher potency benzodiazepines. Older adults are most sensitive to memory effects by benzodiazepines, but often their memory problems are blamed on ageing or may lead to a misdiagnosis of dementia.

It is argued that the increased sensitivity of older adults to memory problems resulting from benzodiazepine use is, in part, attributable to their lower baseline performance. In addition, benzodiazepines have been shown to be the drugs most likely to exacerbate an underlying dementia (Miller 1997). However, it is suspected that cognitive impairment in older adults

may develop insidiously and manifest as a complication following a long period of benzodiazepine use, therefore; problems are not always linked to the drug.

Laboratory experiments have sought to establish which benzodiazepines have increased amnesic effect and impact on reaction time. Table 2 gives a summary of a selection of the published research in this area.

In addition, it is widely accepted that alcohol has powerful amnesic properties, in combination with benzodiazepines, serious effects on memory and related cognitive function have been observed (Subhan and Hindmarch 1983). Benzodiazepines are thought to potentiate the action of sedative CNS depressants such as alcohol. This interaction is of significance because the two drugs are often taken together.

Table 2: Summary of research evidence for memory impairment and decreased reaction time resulting from benzodiazepine use

Hindmarch	1990	Diazepam 5 mg demonstrated a significant impairment (with respect to control subjects) on recall tests and digit span memory tasks. Diazepam 10 mg significantly impaired a paired associate learning task. Diazepam 20 mg produced a significant impairment on recognition tasks.
Gudgeon and Hickey	1981	Diazepam 10-30 mg was found to significantly impair reaction time.
Gier et al	1981	Diazepam 5-20 mg per day significantly impaired overall driving performance of anxious patients.
Biehl Berry et al	1979 1974	Diazepam 10 mg was found to significantly impair brake reaction time.
Betts and Birtle	1982	Temazepam 20 mg was found to significantly impaired gap-judging ability.
Alford and Hindmarch	1987	Nitrazepam 5 mg was found to significantly increase brake reaction time as well as impair performance on other tests of motor car handling; the morning after initial and repeated nocturnal doses
Murphy et al	1982	Nitrazepam 2.5 mg after four consecutive nights significantly impaired a card sorting task in a group of elderly patients; by comparison, an equivalent dose of triazolam had no effect.
Skegg et al	1979	A prospective study carried out in the UK estimated the risk of an accident involving death or injury to be 4.9 times greater when prescribed benzodiazepines are present.
Neutel	1995	Reported a "several-fold excess risk" for hospitalisation resulting from road accident injury following prescription benzodiazepine use.
Ray et al Hemmelgarn et al	1992 1997	Elderly people taking benzodiazepines are significantly more likely to have an injurious motor accident.

Psychomotor effects

Psychomotor effects have been corroborated in laboratory experiments and in real-life driving experiments. Ataxia, lack of coordination and vertigo have been demonstrated (Miller 1997).

In their study examining benzodiazepine use among older adults in the community, Kirby et al (1999) said, "Benzodiazepines with a long duration of action are particularly likely to accumulate and therefore have a greater potential for sedative effects and psychomotor impairment." (p.280). Accumulation is explained by reduced clearance in older adults, which gives rise to higher plasma concentrations.

Of particular concern is the finding that older people have a significantly increased risk of falling (Tinetti et al 1988) and of sustaining hip fractures (Ray et al 1989). The specific problems of benzodiazepine use with older adults will be considered further in Chapter 4.

Psychological effects

Sedation is the desired effect of a benzodiazepine taken at night for sleep problems, but when a benzodiazepine is taken during the day for generalised anxiety or panic disorder, sedation is an unwanted side-effect. Sedation occurs in approximately one-third of patients prescribed benzodiazepines for anxiety disorders (Salzman 1992). Also euphoria can be experienced, especially with particular benzodiazepines such as diazepam. These effects are observed particularly when the benzodiazepine is first commenced, but will be significantly less noticeable after 1 or 2 weeks of daily use. Many patients report that the feeling of sedation appears to "wear off", although often it is that they have stopped noticing the sedation. Long-acting hypnotics, taken at night for sleep, are said to produce residual sedative effects for a large proportion of the following day (Lader 1999).

Many studies have linked suicidal thinking and suicide attempts to benzodiazepine use (Zisook and DeVaul 1977; Miller and Gold 1991), adding weight to the proposal that benzodiazepines can produce deterioration in mood. It has been postulated that because many patients present with features of both depression and anxiety, a reduction in anxiety following administration of benzodiazepines will result in the depressive features appearing more apparent. It is also suggested that in some patients the euphoriant effects of benzodiazepines can disguise depressive symptomatology (Lader 1999). However, there are studies that argue that benzodiazepines do not induce or reduce depression.

Deterioration in affect and social behaviour in long-term benzodiazepine users has been noted by observers but not by the individuals themselves (Griffiths et al 1983). This finding suggests that effects of benzodiazepines may not always be reliably elicited by self-report.

Finally, the use of benzodiazepines to treat stress and bereavement reactions has been found to result in the suppression of traumatic memories, for example physical and sexual abuse. Such traumatic memories can be vividly evoked when the benzodiazepines are withdrawn, often years later (Risse et al 1990). Similarly, benzodiazepines can delay the normal post-traumatic stress reaction (Bond 1990).

Chapter 2: Insomnia and the use of benzodiazepines

Prevalence of insomnia

Insomnia usually means difficulty in falling asleep, disturbed sleep or the experience of sleep, which leaves an individual feeling less than refreshed and feeling tired the next day.

The reported prevalence rates of insomnia vary across studies which predictably suffer from discrepancies in the definition of insomnia. Crook et al (1987) reported that up to 40 per cent of individuals over the age of 65 years complain of disturbed sleep. A Gallup Poll survey (1991) carried out for the National Sleep Foundation reported that 36 per cent of the American adult population said that they had problems with sleep. Twenty-seven per cent of this group said that it was occasional and the other 9 per cent said that they had a chronic sleep problem. More recently Smith et al (2002) reported that 10–15 percent of adults report persistent sleep problems.

Many population-based surveys have reported that the prevalence of poor sleep increases with age. However, an important consideration related to this finding is the extent to which age-related declines in physical health contribute to the reported increase in sleep difficulties. This would also include the contribution of various medications taken to control such physical health problems. A study by Bliwise et al (1992) adjusted for such confounding variables when reporting the prevalence of disturbed sleep in a population, ages 50–65 years. This study found low prevalence of self-reported trouble falling asleep every night or almost every night. Bliwise et al (1992) claimed their findings were lower than most previous published studies and state “This implies that when overall physical health factors are taken into account a decline in sleep quality is not necessarily an inevitable component of ageing per se”. (p.49).

Longitudinal studies of insomnia have attempted to provide information about the stability of insomnia over time. In one study Mendelson (1995) found that “most” patients with chronic insomnia were found to be suffering from the same symptoms 64 months later. In another study Ganguli et al (1996) found that two out of every three older patients that reported insomnia at baseline, continued to report insomnia at 2-year follow-up.

Demographic features associated with insomnia

The following findings are commonly reported demographic features of insomnia:

- Insomnia complaints increase with age (Gallup Organisation 1991).
- Women report more insomnia than men (Mellinger et al 1985).
- Single individuals are more likely to report insomnia than individuals that are married (Karacan and Williams 1983).
- Insomnia is reported more often in individuals of lower socioeconomic status than individuals of higher socioeconomic status (Habte-Gabr et al 1991).

Causes and types of insomnia

The causes of insomnia are broadly categorised as physical, physiological, psychological, psychiatric, and pharmacological (Beaumont 1990). Insomnia is usually classified as transient (lasting a few days), short-term (lasting 1–3 weeks) and long-term (lasting more than 3 weeks). The main differentiation lies between transient and/or short-term and long-term insomnia. Usually, those individuals with transient insomnia are found to have a history of normal sleep prior to a precipitant, the resolution of which results in the return of normal sleep. A wide variety of situations and conditions may provoke transient/short term insomnia.

- Environment related include: unfamiliar sleep environments e.g, noise, temperature, sleep surface, sleep position.
- Stress related: life events.
- Sleep schedule related: disruption of circadian rhythms (e.g. jet lag, shift work).
- Drug related: Drug discontinuation or drug initiation.

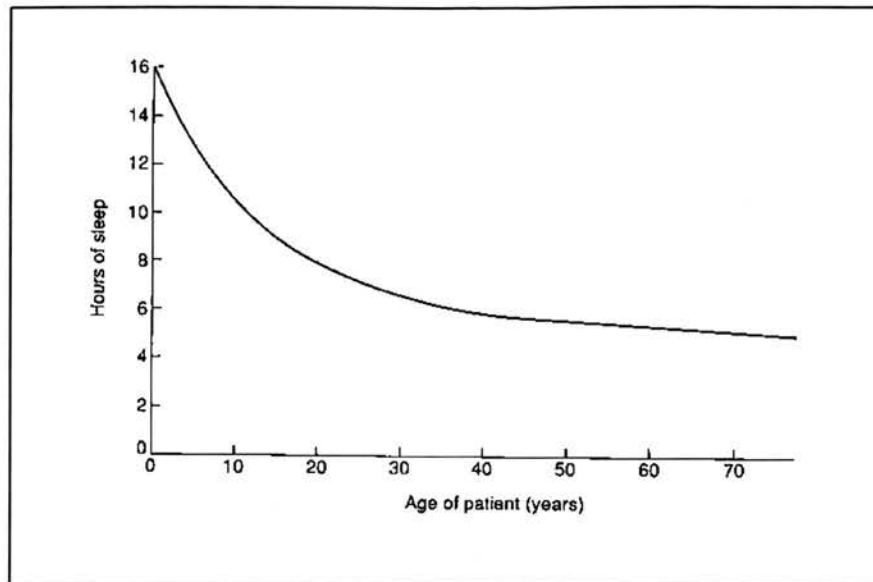
(Roehrs et al 1994).

Chronic long-term insomnia is more usually secondary to other conditions such as physical, psychological or psychiatric conditions. In such cases careful consideration of differential diagnosis is important. When insomnia is clearly the primary problem and not secondary to another condition it is referred to as “Primary Insomnia” (DSM-IV 1994). This classification does not mean that the individual is free from any other psychiatric or medical conditions, but that these other conditions are not the cause of the insomnia. Primary insomnia includes some of the less common sleep disorders which usually require more specialised treatment from a sleep disorders clinic; examples of such types of sleep disorders would include, sleep apnoea/hyponolea syndrome, narcolepsy, penodic limb movement syndrome.

The effect of age on sleep requirement

As mentioned above, as a group, it is older adults that present more frequently with complaints of insomnia, with the result that medication is used most with this group (Clift 1993). It is argued that older patients place an increase value in sleep because it reduces loneliness and boredom and many older people do not appreciate that the number of hours of sleep required by an individual reduce with age.

Figure 1: Graph to show sleep requirements lessen with age (Clift 1993)



The real difference in nocturnal sleep across age groups would appear to be as a result of changes in patterns of sleep. In the older person daytime napping is most notable. When total hours of sleep over 24 hours are calculated there is often very little difference between the total hours of sleep of an older person and younger person.

However, sleep stage patterns do change with age. The percentage of rapid eye movement (REM) sleep is inversely correlated with age (Benca et al 1992), but it is slow wave non rapid eye movement (NREM) sleep that decreases most dramatically with age (Reynolds et al 1991). NREM sleep comprises stages 1–4, with stage 4 being the “deepest” sleep. Stage 3 sleep and stage 4 sleep decrease with age until; for most older people, stage 4 sleep is absent. Because older people experience very little of the “deeper” sleep stages, this is a likely explanation for their more frequent nocturnal awakenings.

The use of benzodiazepine hypnotics for insomnia

The first psychotropic drugs to be used for sedation were the bromides (1870s). By the turn of the century these drugs were replaced with barbiturates following the introduction of barbitone (1903). The first benzodiazepine marketed as a hypnotic was nitrazepam (1965).

Since the 1960s, benzodiazepines have remained the most widely prescribed drugs for sleep problems. Whilst short-term use of benzodiazepine hypnotics are very effective in inducing sleep, the sleep they induce is not the same as natural sleep. Benzodiazepines reduce sleep onset, decrease nocturnal awakenings and therefore increase total sleep duration. However, they alter normal sleep pattern (sleep architecture).

Stage 2 sleep (which is fairly light sleep) is increased and accounts for most of the increase in sleep duration. However, stages 3 and 4 and REM sleep are reduced (Wheatley 1981). These typical changes in sleep stages occur for most patients, although some variation is observed according to dosage, the length of time an individual has been in receipt of benzodiazepines, type of benzodiazepine and age.

A meta-analysis of benzodiazepine use in the treatment of insomnia carried out by Hobbrook et al (2000) analysed data from 45 trials, representing 2672 subjects. Analysis of sleep records revealed that when compared with placebo, benzodiazepines reduced sleep latency by 4.2 minutes (non-significant). This figure differed from the self-reported estimates of sleep latency, in that the patients reported that sleep latency was reduced by 14.3 minutes when benzodiazepines were used. Compared with placebo, benzodiazepines significantly increased total sleep duration by 61.8 minutes. The meta-analysis also found that patients receiving benzodiazepine treatment reported adverse effects, which included daytime drowsiness, dizziness or light-headedness, in addition benzodiazepine use was associated with cognitive impairment. However, these adverse effects did not translate into increased discontinuation rates.

In another meta-analysis (Smith et al 2002) pharmacotherapy was compared with behaviour therapy for persistent insomnia; 21 studies representing 470 subjects were analysed. The meta-analysis concluded, “overall, behaviour therapy and pharmacotherapy produce similar short-term treatment outcomes in primary insomnia” (p.5). Comparison of outcome variables found the following treatment effects:

- Sleep latency was reduced by 30 percent by pharmacotherapy compared with a 43 per cent reduction by behavioural interventions.
- Both treatments reduced nocturnal awakenings by one.
- Wake time following sleep onset was reduced by 46 per cent with pharmacotherapy and 56 per cent with behaviour therapy.
- Pharmacotherapy increased total sleep duration by 12 per cent and behaviour therapy increased total sleep duration by 6 per cent.
- Pharmacotherapy improved sleep quality by 20 per cent and behaviour therapy improved sleep quality by 28 per cent.

(Smith et al 2002).

Tolerance to benzodiazepine hypnotics is reported to take place more quickly than the anxiolytic drugs (Aston 1994). The decision to select long-term or short-term hypnotics has been much debated as each has advantages and disadvantages over the other. Short half-life hypnotics such as temazepam are less likely to leave a patient feeling “hung over” the next morning, a common feature of nitrazepam, which has a long half-life. But the problem with the more rapidly eliminated benzodiazepines such as temazepam is that of rebound effects. Rebound effects can cause early morning waking and anxiety during the following day because the drug has been quickly eliminated from the body. It is not unusual to find patients increasing their nightly dose of temazepam or taking another dose during the night when they wake up. Problems with the longer-acting benzodiazepines such as nitrazepam include

the residual effects, especially in older adults, which are associated with impairments of performance tasks the next day. Residual effects arise because of incomplete elimination of the drug and/or their pharmacologically active metabolites, in some cases resulting in accumulation in the body.

The UK Committee on Safety of Medicines (1988) and the Royal College of Psychiatrists (1988) recommend that benzodiazepines should only be prescribed for insomnia when “it is severe, disabling or subjecting the individual to extreme distress”. Nevertheless, prescribing rates have remained fairly constant despite a reduction in the prescribing rates of anxiolytics. Recommended dosage schedules are show below in Table 3.

Table 3: Rational use of benzodiazepines in insomnia

Type of insomnia	Dosage and administration
Transient insomnia (e.g. disruption of circadian rhythm)	1–2 nights only. Minimal dosage (usually not more than diazepam 2–5 mg or equivalent)
Short term insomnia (e.g. temporary environmental stress)	Not for more than 2 weeks. Intermittent is possible (1 night in 2 or 3 nights). Minimal effective dosage (start with small dose, increase if needed, usually not more than diazepam 10 mg or equivalent)
Chronic insomnia (e.g. secondary to physical, psychological or psychiatric causes)	Treat primary cause first. Intermittent treatment if possible. Not more than 2 weeks (course may be repeated after an interval). Minimal effective dosage (as above)

(Source: Aston 1994)

Medical conditions and the effect on insomnia

Insomnia often develops as a result of medical conditions that cause pain and discomfort. In addition, many physical conditions evoke an emotional response, which can give rise to anxiety and depression. Emotional responses such as anxiety can further exacerbate symptoms of a physical condition, as demonstrated in painful conditions such as arthritis or

duodenal ulcer. Many medical conditions such as cardiovascular and pulmonary disorders and thyroid dysfunction are shown to cause changes in sleep architecture (Kales and Kales 1984). In addition, a variety of medications can cause insomnia, either as a result of administration or withdrawal. Certain drugs have a direct effect on the central nervous system and others cause insomnia through their side-effects.

A study by Kuppermann et al (1995) examined the prevalence of sleep problems and their correlates in a working population (mean age 36 years). Two groups were compared; individuals reporting no current sleep problems and individuals reporting sleep problems (*N* = 588). Of the range of physical conditions reported by respondents across both groups, four conditions were found to feature at significantly higher prevalence rates in the group that had sleep problems. In addition, a screening instrument for mental health problems (Mental Health Index) revealed that the group with sleep problems also reported significantly higher symptomatology indicative of mental health problems. Table 4 reports the prevalence of the significant correlates of sleep problems.

Table 4: Correlates of sleep problems: percentage prevalence for sleep problem and no sleep problem

<u>Physical conditions</u>	<u>Group one</u> no current sleep problem	<u>Group two</u> current sleep problem
Gastrointestinal problems	8.5 per cent	16.2 per cent *
Headaches	15.2 per cent	43.7 per cent *
Muscle pain	18.8 per cent	37.0 per cent *
Neck or back pain	24.9 per cent	44.2 per cent *
<u>Possible mental health conditions</u>	10.4 per cent	42.0 per cent *

(* Significantly higher than group one)

Source: Kuppermann et al (1995)

The Kuppermann et al (1995) data highlight the predominance of pain or discomfort as a feature of those physical conditions that contribute most to poor sleep.

Another study examined correlates of insomnia in patients with chronic illness (Katz and McHorney 1998). In this study, the mean age of respondents ($N = 3445$) was 54 years. The following list of conditions were found to be significantly associated with insomnia:

Physician diagnosed conditions	Patient-reported comorbidities,
▪ Major depression,	▪ Angina,
▪ Sub-threshold depression	▪ Obstructive airways disease,
▪ Myocardial infarction	▪ Back problems
▪ Congestive heart failure	▪ Hip impairment
▪ Diabetes mellitus.	▪ Osteoarthritis
	▪ Prostate problems.

This study also reported that “there was no significant association between age and insomnia after controlling for the presence of chronic conditions.” (p.1103).

In summary, it would appear that disruption to sleep arises from a complex interaction of physical and emotional factors. According to the published research, the experience of pain associated with many medical conditions can both exacerbate anxiety and depression or be exacerbated by anxiety and depression, both of which add to sleep difficulties. In addition to painful conditions there is a range of other chronic medical problems that can cause disrupted sleep. The medications used to treat such conditions can further contribute to sleep disruption. It would be reasonable, therefore, to postulate that with advancing age, health problems will play an increasingly significant role in insomnia, because of the correlation between ageing and increased ill health.

The role of psychiatric factors in insomnia

The relationship between insomnia and psychiatric disorders is well researched, especially as diagnostic criteria for some psychiatric disorders are characterised by the inclusion of sleep disturbance symptoms. It has also been proposed that psychiatric disorders are frequently under-diagnosed in individuals presenting with insomnia (Tan et al 1984). Following an examination of epidemiological data, Ford and Kramerow (1989) suggested that, of those individuals reporting insomnia, up to 57 per cent may have a psychiatric condition or present with a psychiatric condition, within a year.

The finding that chronic insomnia can be a causal factor in psychiatric disorders is explained in terms of the presence of chronic insomnia becoming a stressor, a common precipitant in the development of psychiatric problems. Table 5 reproduces data from a study by Breslau et al (1996) which examined the prior history of sleep disturbance and subsequent onset (during a 3½ year follow-up period) of psychiatric disorders in a sample of young adults ($N=979$).

Table 5: Incidence and gender adjusted odds ratios of new psychiatric disorders by prior history of insomnia

	Insomnia	No insomnia	OR (95 per cent CI)
Major depression	15.9 per cent	4.6 per cent	3.95 (2.22–7.00)
Any anxiety*	13.7 per cent	7.1 per cent	1.97 (1.08–3.60)
Alcohol abuse	7.1 per cent	4.7 per cent	1.72 (0.85–3.52)
Drug abuse	4.1 per cent	0.6 per cent	7.18 (2.13–24.17)
Nicotine dependence	17.8 per cent	8.2 per cent	2.41 (1.46–3.97)

(*Any anxiety includes GAD, panic disorder, OCD and any phobia)

Source: Breslau et al 1996

One could speculate that the development of drug problems is a more likely outcome in a younger population, from which these data were gathered.

Mood disorders

The incidence of disturbed sleep in mood disorders is pervasive across all subtypes and is therefore a diagnostic symptom for each. It is considered unusual to find a patient with mood disorder who does not experience disrupted sleep-wake patterns, with the most commonly reported being insomnia rather than hypersomnia.

Major depression is associated more often with early morning awakenings and dysthymic disorder with frequent arousals and sleep onset difficulties (Walsh et al 1994). Not only is insomnia a feature of depression, but also it has been shown to be a predictor of the development of mood disorders. A study by Livingston et al (1993) sought to answer the question – “Does sleep disturbance predict depression in elderly people?” The following extract summarises the main finding of this study:

“The best predictor of future depression in elderly people who were not depressed was current sleep disturbance. In the presence of current sleep disturbance, the traditional predictors of depression - being a woman, having a disability, being unmarried, living alone and being older - did not contribute further. This study has shown that sleep disorder is associated with pathology.” (p.445)

Anxiety disorders

The published research would appear to suggest that within samples of individuals with sleep difficulties the prevalence of anxiety disorders is lower than for mood disorders. Walsh et al (1993) argues that anxiety symptoms are frequently considered secondary to mood disorder symptoms. He argued that when depressive symptomatology is present, the resulting diagnosis will usually be one of affective disorder.

Nevertheless, two anxiety disorders include sleep disturbance as a diagnostic symptom. Patients with generalised anxiety disorder often have sleep initiation difficulties. Patients with post-traumatic stress disorder also report difficulty in sleep initiation but also experience sleep maintenance problems, very often because of bad dreams or nightmares.

Somatoform disorders

The most common somatic problems are reported to be insomnia, headache, irritable bowel syndrome and hypochondriasis (Salkovskis 1999). The common feature in insomnia related to somatisation is that of worry and subsequent increased arousal. There is a paucity of published research reporting the prevalence of somatisation in insomnia and it is possible that somatisation is often labelled as generalised anxiety. Mellinger et al (1985) reported that 37 per cent of patients with severe insomnia and 19 per cent of patients with mild insomnia scored highly on a somatic anxiety scale, in contrast with 6 per cent of good sleepers.

Chapter 3: Anxiety and the use of benzodiazepines

Anxiety comprises three systems: (i) physical symptoms (ii) cognitions and (iii) behavioural changes. These three systems are closely inter-related, with each affecting the development and maintenance of the others.

Anxiety states form a number of recognised anxiety disorders, each having their own diagnostic criteria (found in DSM-IV and ICD-10). Generalised anxiety is the most common of the anxiety disorders. Prevalence rates vary across published research, although some consistency is observed. For example, from a general population survey, Weissman and Merikangas (1986) reported 1-year prevalence rate for generalised anxiety disorder of 3–6 per cent and a 1-year prevalence rate for panic disorder in the range of 0.5–3 per cent. Similarly, from a general population study, Uhlenuth et al (1983) estimated prevalence of generalised anxiety disorder to be 6.4 per cent with prevalence of panic, agoraphobia and other phobias to be 3.5 per cent.

In some disorders, such as post-traumatic stress disorder (PTSD), the precipitant to the development of anxiety is clearly a major life event(s) or trauma. However, for others the reasons for their development are less evident. Vulnerability to stress through genetic and environmental factors can predispose individuals to anxiety problems and very often anxiety symptoms can be traced back to childhood and young adulthood. However, there are exceptions to this; for example, specific phobias often develop without any prior history of anxiety.

The management and treatment of anxiety regardless of classification or cause is most effectively carried out using psychological rather than pharmacological measures (Hackman 1993). Two anxiety disorders more frequently treated with benzodiazepines include generalised anxiety disorder (GAD) and panic disorder (PD).

Anxiety disorders and older adults

The average age of the participants in the current study is 72 years, therefore consideration of anxiety in this age group is particularly relevant. Recent studies suggest that anxiety disorders are the most common mental health disorders in older people (Blazer 1997, 2002). Community based prevalence estimates of anxiety in older adults suggest that 11.4 per cent of adults over 55 years meet the criteria for an anxiety disorder in 1 year (Flint 1994)

Woods (1996) argued that some specific phobias are particularly common to older adults. For example, fear of crime, fear of dying and fear of falling. Fear of falling is the most prevalent fear of older people (Howland et al 1993).

The use of benzodiazepines for anxiety

Prescribing recommendations for the use of benzodiazepines in the treatment or control of anxiety are similar to the prescribing guidelines for benzodiazepine use with insomnia. The Committee on Safety of Medicines (1988) advised that benzodiazepines “are indicated for the short term relief (2–4 weeks only) of anxiety that is severe, disabling or causing unacceptable distress”. Aston (1994) suggested that this advice had been acted upon in the United Kingdom, reporting that yearly prescriptions for anxiolytic benzodiazepines have reduced from a peak of 18 million in 1978, to below 10 million by 1994.

Benzodiazepines, as in insomnia, provide only symptomatic relief in the treatment of anxiety. The literature highlights the use of specific benzodiazepines for generalised anxiety and panic disorder.

Many clinicians believe that the use of benzodiazepines in the long-term treatment of GAD is justified because this disorder results in significant functional impairment (Rosenbaum and Gelenberg 1991). The benzodiazepine of choice for GAD is one that provides a smooth onset of action, with relatively slow absorption and elimination rates, so that fluctuations in plasma

concentrations are minimised. However, as will be discussed in Chapter 4, this type of benzodiazepine is potentially more problematic for older adults, because benzodiazepines with a longer elimination half-life are more likely to be associated with cognitive impairment, falls and road traffic accidents in the elderly.

A number of benzodiazepines have also been used in PD, as have tricyclic antidepressants and monoamine oxidase inhibitors. Of the benzodiazepines used in the treatment of PD, the literature reports that alprazolam is more successful than other benzodiazepines; alprazolam is a high-potency benzodiazepine with a short elimination half-life. Nevertheless, according to Sheeham et al (1984) as with other pharmacological treatments, cessation of medication in PD is followed by relapse in 80 per cent of cases. This outcome leads to long-term use, which can lead to dependence, tolerance and withdrawal symptoms. Psychological treatment in the form of exposure work has been shown to reduce relapse and improve long-term outcome in PD. However, it is important to be aware that there is evidence which demonstrates that the simultaneous use of benzodiazepines can interfere with psychological treatments (Marks and O'Sullivan 1989).

Chapter 4: Older adults: relevant considerations

Reference to “older” adults in the current text uses the United Nations example, also adopted by the World Health Organisation, of age 60 years to describe “older” people. However, it is important to acknowledge that chronological age is not an absolute marker for the features of ageing (WHO 2002).

Older adults are a growing section of society (Kinsella and Velkof 2001). Whilst this large proportion of society should not be regarded as separate from younger adults, advancing age brings particular challenges. These challenges include coping with general medical conditions, the need for an increased amount of medication and psychosocial stressors such as bereavement and isolation (WHO 2002). With regard to mental health problems, younger and older adults are affected by many of the same disorders, although often prevalence, the features of, and the course of mental health problems can differ.

Mental health problems in older adults

The Report of the Surgeon General (1999) reviewed mental health in older adults proposed that the detection of mental illnesses is more difficult in older persons. The report stated: “Many older individuals present with somatic complaints and experience symptoms of depression and anxiety that do not meet the full criteria for depressive or anxiety disorders... detection of mental disorders in older adults is complicated further by high comorbidity with other medical disorders.” (p.340).

The published literature suggests that depressive symptoms are the most prevalent of mental health problems (Report of the Surgeon General 1999). Beekman et al (1999) carried out a review of community-based studies and reported an average prevalence of 13.5 per cent for depressive symptomatology. However, the key issue in depression in older adults (as well as

other psychiatric disorders) is that of under-diagnosis and under-treatment. Katon et al (1992) examined the use of antidepressant medication for depression in older adults and found that only 11 per cent received adequate antidepressant treatment, 34 per cent received inadequate treatment and 55 per cent received no treatment.

In terms of the diagnosis of anxiety, a similar picture to that of depression is reported in that many older adults present with anxiety symptoms that do not satisfy diagnostic criteria for specific anxiety disorders, with the outcome that anxiety is left untreated. Katona et al (1997) found such high rates of comorbid generalised anxiety with depression; they concluded that depression should be considered whenever anxiety is observed in older adults.

Benzodiazepines and older adults

Despite the guidelines and the multinational trend towards reduced prescribing of benzodiazepines, particularly anxiolytics, older adults continue to use prescribed benzodiazepines at rates very similar to those they always have. Ticehurst (1995) said, "After tobacco and alcohol, benzodiazepine consumption is associated with the greatest risk of abuse and dependence in the elderly" (p.187). According to Ancill and Carlyle (1993) the most likely long-term benzodiazepine user is the elderly female.

Because anxiety in older adults can be difficult to differentiate from other conditions such as depression, physical disability and cognitive dysfunction, it is of paramount importance that the underlying cause of anxiety is established prior to commencing anxiolytic medication, otherwise the cause may be masked and not adequately treated. However, it is in the treatment of insomnia in older adults that benzodiazepines are most frequently prescribed.

Older adults are especially sensitive to the adverse effects of benzodiazepines and there are a number of issues that are specific to the older adult population, which must be considered when prescribing benzodiazepines to this group of patients.

Drug metabolism

Drug absorption mechanisms change with ageing. In older adults higher brain benzodiazepine levels are said to result from decreased protein binding and greater blood-brain barrier permeability (Ancill and Carlyle 1993). In addition, drug accumulation arises from declining lean body mass and slowed metabolism and excretion. However, it has been shown that once tolerance has occurred, the extent of accumulation is not reflected by an increase in sedation (Teboul and Chouinard 1990). This is a worrying feature of benzodiazepine use with older adults because it allows accumulation to go unnoticed, sometimes with serious consequences for this client group.

The effect of chronic illness

Kusserow (1989) reported that 80 per cent of adults over 65 years have one or more chronic illnesses. Therefore, benzodiazepine prescribing in older adults should not occur in isolation from their coexisting medical pathologies. Medical pathology and the medications used to treat such conditions can have an impact on efficacy and toxicity of benzodiazepine medication. According to Ancill and Carlyle (1993) cardiovascular, metabolic, hepatic and renal pathologies can increase the risk of toxicity, but can also be an underlying cause of the presenting anxiety.

The additive properties of benzodiazepines when used with other central nervous system depressant drugs, is one of the most common forms of interaction between benzodiazepine medication and other medications used to treat or control chronic illnesses in older adults. Examples include alcohol, other hypnotic agents and some antidepressants, which can cause varying degrees of sedation. In addition, benzodiazepines are also known to increase the levels of certain drugs; one such example is digoxin, a medication prescribed for cardiovascular problems (Bernstein 1988).

Falls and hip fractures

A significant amount of published research has highlighted the problem of the increased risk of falls (Sorok and Shimkin 1988), hip fractures (Ray et al 1989) and motor vehicle crashes (Hemmelgarm et al 1997) in older people taking benzodiazepines. It is widely accepted that the half-life of the benzodiazepine prescribed makes a significant contribution in this finding, with longer half-life benzodiazepines believed to cause more accidents owing to longer elimination times. Ray et al (1989) reported that the risk of fractures from falls when long compared with short half-life benzodiazepines were used was 1.7 and 1.1 per cent respectively. Falls in older age give rise to a higher risk of disability and death (WHO 2002). Benzodiazepine use has also been linked to osteoporosis in older adults. It has been proposed that benzodiazepines may act as chelators when combined with iron and this can affect calcium intake, with the result that bone mineral reserves are depleted (Harrison and McNeill 1988).

Benzodiazepine choice

In summary, choosing which benzodiazepine to prescribe in the older adult client group is complicated by the greater potential for adverse effects. As mentioned earlier the incidence of hip fracture has been linked to the longer-acting benzodiazepines, such as nitrazepam and flurazepam, owing to increased hang-over effects. The longer-acting benzodiazepines also cause increased accumulation because of changes in drug metabolism with advanced age. The use of short-acting benzodiazepines such as lorazepam and triazolam is not advisable on a long-term basis following concerns of cognitive impairment and amnesic effects. Finally, benzodiazepines can also interact with other medications used in the treatment of chronic conditions.

Therefore, Tinetti et al (1988) argued that the use of benzodiazepines warranted careful consideration in the older adult population, especially if there was increased risk of dementia, visual impairment, postural hypotension and neurological and musculoskeletal disability.

Chapter 5: The use of benzodiazepines in general practice

The general trend in prescribing rates for benzodiazepine medication by general practitioners has shown a gradual decrease over the past 20 years (Simpson 1993). Nevertheless, despite the magnitude of published evidence demonstrating the dependency potential of benzodiazepines, the downward trend has been relatively slow. Wright (1991), in an editorial about general practitioners and psychiatry, argued that the bulk of psychiatric and psychological problems are seen and managed by general practitioners alone. He added that many general practitioners have limited training in psychiatry and the problem of restricted resources often afford them little recourse to make a referral to appropriate resources. This does not excuse the over-prescribing of benzodiazepines but offers an explanation. Whilst most general practitioners acknowledge that the use of benzodiazepine medication should be avoided wherever possible, they often have little by way of alternative options.

Prevalence of long-term benzodiazepine use in community/general practice studies

A study by Rodrigo et al (1988) examined the health of long-term benzodiazepine users and included prevalence rates of long-term use from a number of other studies. The Rodrigo et al study reported prevalence of long-term use (mean 5 years) at 2.2 per cent in a practice population of 3741. This finding was comparable to other studies reviewed by Rodrigo et al which ranged from 1.6 per cent to 3.1 per cent; all were general practitioner samples. However, these figures represent all adults in each general practice. Because the largest group in receipt of benzodiazepines are older adults it is important to consider prevalence rates in adults over 65 years.

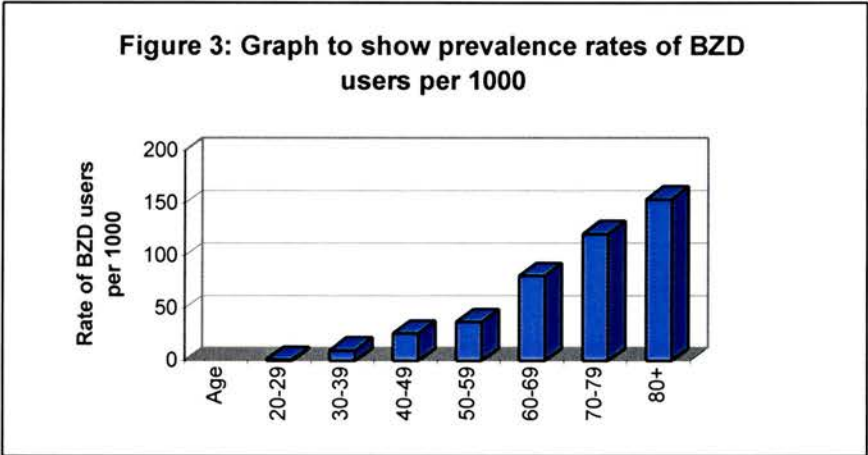
Kirby et al (1999) reported a prevalence rate of benzodiazepine use in older adults of 17.3 per cent ($N = 1701$) in an Irish community sample. A longitudinal study by Taylor et al

(1998) collected data from an urban sample in Liverpool on two occasions. Taylor et al found that in the period 1982–83 the prevalence rate of benzodiazepine use in adults over 65 years was 12.8 per cent ($N=1070$) and in the period 1989–91 the prevalence rate was found to be 10.8 per cent ($N=5490$).

Patient characteristics in primary care

Age

Simpson et al (1990a) reported the following age-band prevalence rates of long-term benzodiazepine users, shown in Figure 3.



(Source: Simpson et al 1990a)

Physical health:

The Forth Valley GP Research Group (Simpson et al 1990b) examined three general practices in central Scotland, comprising a total of 17,000 patients. A matched subsample (age and sex) of long-term benzodiazepine users and controls were assessed for physical morbidity, the authors concluded that:

“Patients receiving hypnotics only were older, had a history of more physical illness and had received more non-psychotropic medication than patients receiving anxiolytics only.” (p.22)

The physical conditions found to be significantly more prevalent in long-term benzodiazepine users were cardiovascular; gastrointestinal; genitourinary; respiratory; central nervous; ear, nose and throat (Simpson 1990b), this finding reflects similar findings reported in Chapter 2. However, it would appear that whilst physical morbidity is closely linked to long-term benzodiazepine use across all ages, particular health problems across age groups vary with the presence of a broader range of health problems found in older adults. This is not particularly surprising when one considers that ageing is associated with the development of more physical health problems.

There are occasions when benzodiazepines are indicated for a physical condition. The most common example of which in the primary care setting would be in controlling muscle spasm that causes pain or discomfort. However, as a psychotropic medication, it is in the treatment of psychiatric and psychological problems that benzodiazepines are predominantly associated.

Psychiatric problems

The two main problem areas for which benzodiazepines are prescribed in general practice are anxiety and insomnia. As reviewed in Chapter 2 comorbidity with other psychiatric disorders is common in long-term benzodiazepine users. Of particular significance is the prevalence of depression, anxiety and somatisation which are often masked by insomnia. The under-diagnosis of depression in general practice is common, particularly in older patients (Unutzer et al 1999). The characteristics and problems associated with benzodiazepine use in a primary care population are difficult to quantify because of the inter-relationship of causal factors. Research has also shown that sleep problems can predict subsequent psychopathology, particularly depression. Faced with the range of possible combinations of factors it is difficult to establish causal relationships when a patient presents with more than one problem, such as anxiety, depression, insomnia, pain and discomfort, and physical health anxiety. The use of benzodiazepine medication often serves to further

complicate the relationship between these factors by masking symptomatology and creating new symptoms by means of rebound, withdrawal and the effects of drug accumulation.

Reduction of long-term use of benzodiazepines in primary care

In a study of chronic benzodiazepine use in a primary care population, Bashir et al (1994) asked general practitioners why they continued to prescribe benzodiazepine medication. The two most commonly reported reasons given were (i) “because the patient wished to remain on benzodiazepines” and (ii) “that it was too much of a struggle for the patient to come off the tablets”.

In a community survey of long-term daytime use of benzodiazepines, Wright et al (1994) found that almost half their subject sample wished to continue taking their medication. In addition, they found that the desire to stop using benzodiazepine medication varied across age groups. A difference was demonstrated between patients over 60 years and those under 60 years, with those over 60 years significantly more likely to express a desire to continue taking their medication. Similarly, Hawley et al (1994) found that patients from a general practice population were “relatively old and exhibited a conspicuous lack of interest in having any help with their chronic drug (*benzodiazepine*) use” (p.794). A further study by Linden et al (1998) examined long-term, low-dosage use of benzodiazepines, and found that two-thirds of a primary care sample ($N=122$) rejected a drug-holiday proposal.

Although the published research reveals that benzodiazepine prescribing demonstrates a downward trend, use of hypnotic benzodiazepines in the older adult population has remained more static than the use of anxiolytic benzodiazepines in the general population. Morgan and Clarke (1997) suggest the reason for this could be because benzodiazepines are used more frequently as a hypnotic medication with older adults and the incidence of sleep problems is

higher in older adults. Further evidence that anxiolytic use has reduced more rapidly than the use of hypnotics, was demonstrated in a study by Taylor et al (1998). This longitudinal study reported that during a 6–8 year period the prevalence of hypnotic benzodiazepine use in adults over 65 years barely changed from 8.8 per cent to 8.5 per cent. The prevalence of anxiolytic benzodiazepine use in adults over 65 years reduced from 5.5 per cent to 3.2 per cent.

To conclude, despite well-established prescribing guidelines, which state that *benzodiazepines should not be used for more than 4 weeks, and then at only the lowest possible dose to control symptoms*, in 1995 Jago reported that 85 per cent of the 13.1 million prescriptions written annually in the UK for hypnotic medication were for more than 28 days.

In summary, the research highlights that the largest cohort of benzodiazepine users in primary care are older adults, of whom the vast majority take hypnotics for insomnia and have done so for many years. This cohort is more likely to have diagnosed chronic health problems for which they are in receipt of a range of medications. It is also likely that this older cohort, as well as the rest of the benzodiazepine using population in primary care, will have elevated levels of psychopathology. Finally, primary care recipients of benzodiazepine medication would appear to be reluctant to reduce or stop taking benzodiazepines.

Variables to be assessed in long term benzodiazepine users

The preceding chapters have endeavoured to introduce and review a proportion of the breadth of research literature surrounding the benzodiazepines and have highlighted a range of features and issues relevant to long-term benzodiazepine use in a primary care setting.

Based on this review, the prevalence and relationship of three key variables will be examined in the context of long-term benzodiazepine use: dependence, psychopathology and insomnia. In addition a fourth variable was selected which has not (to the author's knowledge) been previously considered in relation to long-term benzodiazepine users: psychological mindedness.

Dependency

Having established that benzodiazepine dependence is an important contributory factor in patterns of benzodiazepine use, the consideration of dependency within the context of the current study cannot be overlooked.

The participants in the pilot study frequently remarked that because their medication was prescribed by a doctor it "must be safe" and that usually any suggestion that their benzodiazepine medication could be "addictive" was rebuked. It would therefore be prudent to avoid any use of the words "addiction" and "addict" in the present study.

In addition, because the daily benzodiazepines users in the pilot study reported that they had never attempted to stop their benzodiazepine medication, it was quite likely that they had never experienced withdrawal symptoms and would be unaware of the potential for this occurrence. A measure of dependency that focused primarily on psychological dependence and did not include items that emphasised withdrawal symptoms or questions about tolerance was considered preferable. Also, because the participants might be defensive about

the suggestion of dependency, these types of questions would need to be phrased in a non-judgemental and non-threatening way.

Psychopathology

The aim of the current study was to investigate the presence of a range of psychopathology in benzodiazepine-using patients. This would include not only depression and general anxiety but also other symptoms such as somatisation, which has rarely been considered in previous studies of this type. Fuentes and Cox (2000) wrote that assessment of somatisation was particularly relevant in anxious older adults “due to suggestions in the literature that older adults may somatise their psychopathology” (p.301).

Insomnia

Insomnia is a key issue in the current study and is discussed at length in Chapter 2. Assessment of sleep pathology is an important consideration.

Psychological mindedness

Psychological mindedness is introduced as a variable worthy of consideration in the current study.

Chapter 5 examined benzodiazepine use in primary care and highlighted the finding that a considerable proportion of long-term benzodiazepine users, usually older adults, are resistant to consider cessation of their benzodiazepine medication. Similarly the pilot study, which precedes this study, found that less than 50 per cent of participants were prepared to consider stopping their benzodiazepine medication. Any one of a number of factors may explain an individual's reluctance to reduce or stop using benzodiazepines, for example:

- A belief that they would be unable to sleep without their sleeping tablets
- Psychological and/or physiological dependence
- Lack of awareness of the potential problems of long-term use
- Medication compliance

The pilot study also found that not all long-term benzodiazepine users took their benzodiazepines every day, but that some users only took them when they felt they “needed too”.

The construct of “locus of control” may be relevant to the question of why some individuals may decide to stop taking their benzodiazepine medication and others would not, and why long-term benzodiazepine use does not necessarily mean daily use. Locus of control (Rotter 1966) is used to explain the extent to which a person perceives events/situations as being a consequence of their own behaviour. In addiction research, the concept of locus of control has been widely researched in an attempt to establish whether individuals high on internal locus of control are better able to control their substance use than those individuals with high external locus of control. The published literature in addiction research presents conflicting reports regarding the usefulness of the Internal-External locus of control dimension (Davies 1992). However, the locus of control dimension does appear to have some value in predicting behaviour change, especially in health settings. This has led to the development of a number of different scales to measure perceived control and responsibility for individual behaviour, with particular emphasis on health-related behaviours and beliefs.

A psychological variable that has at times been conceptualised in a similar way to locus of control is that of psychological mindedness. For example, Rogawski (1982) states that “the highest level of psychological mindedness is the ability to verbalise one’s internal experience as a product of one’s own mind and passions and not as caused by, or the responsibility of,

another” (p.109). This description of psychological mindedness is similar to the way locus of control has been conceptualised.

Psychological mindedness has long been considered relevant (by clinicians) in predicting therapeutic outcome. However, it is a concept that has suffered from a lack of clear definition and as such has given rise to a range of interpretation and has proved difficult to operationalise. The origins of psychological mindedness are found in psychoanalytic writings under “indications for psychoanalysis” (Appelbaum 1973). More recent attempts to define psychological mindedness are reviewed by Hall (1992), who highlights the variation in descriptive terminology. Nevertheless, the general theme is one of psychological understanding of oneself.

Appelbaum’s (1973) definition is probably the most frequently quoted definition in the published literature on psychological mindedness, and is arguably the most comprehensive yet succinct:

“A person’s ability to see relationships among thoughts, feelings, and actions, with the goal of learning the meaning and causes of his experiences and behaviour.” (p.36).

Psychological mindedness was chosen for inclusion in the current study as, potentially, it may explain differences in patterns of benzodiazepine use not otherwise explained by psychopathology and insomnia. Contrary to the study of locus of control, psychological mindedness has not been incorporated into studies of this type.

There are a limited number of measures to assess psychological mindedness, which have been empirically tested. The author considered three of the better-known measures of psychological mindedness (Conte and Ratto 1997), from which the Psychological Mindedness Scale (PMS) was selected. The PMS was devised by Conte et al (1990) and conceives psychological mindedness as the ability to access one’s own and other’s feelings and utilize these for behaviour change.

Summary and Hypotheses

Summary

The introductory chapters of this thesis have endeavoured to introduce the main topic areas associated with the long-term use of benzodiazepines in a primary care population. The salient issues drawn from the published research include evidence that long-term use of benzodiazepine medication results in dependence, tolerance, withdrawal symptomatology, and reduced pharmacological efficacy. In addition, long-term use of benzodiazepines can have adverse effects on cognitive, psychomotor and psychological functioning. As a result of these problems, prescribing guidelines clearly discourage the long-term use of benzodiazepines. However, whilst these guidelines have effected some reduction in long-term use during the past 20 years, prevalence rates have reduced more slowly for hypnotic benzodiazepine medication, especially in older adults, than for anxiolytic benzodiazepines. This is particularly worrying when one examines the breadth of literature that reports the potentially detrimental consequences of long-term benzodiazepine use with older adults.

In the primary care setting the most frequent use of benzodiazepine medication is found to be with older adults that present with insomnia. The treatment of insomnia with hypnotics is therefore considered in more detail than the use of anxiolytics for anxiety. In addition, the evidence of significance physical health problems and psychiatric comorbidity in long-term benzodiazepine users is an important and relevant issue.

Establishing causal and maintaining factors in long-term benzodiazepine use is beyond the scope of this study. However, the intention of the study is to explore a number of hypotheses derived from the issues highlighted in the literature review. These hypotheses seek to

demonstrate a common psychological profile for this cohort, which could be used to inform treatment options and future prescribing practice with primary care patients.

This research study differs from existing published studies because it incorporates a number of different but potentially related variables. Previous studies have focused on a narrow range of psychopathology associated with benzodiazepine use and have neglected the possibility of confounding elements comprising long-term benzodiazepine use. This study considers a wider range of variables involved in long term benzodiazepine use, including insomnia, benzodiazepine dependence and relevant psychiatric disorders such as anxiety, depression and somatisation. The study also examines the demographic features of the sample in relation to each variable and acknowledges the potential influence of chronic medical health problems and chronic pain.

In addition, the concept of drug “dependence” arising from the long term prescription of benzodiazepines has rarely been considered in either older adult samples or primary care samples, the current study combines both these cohorts.

Finally, the study aims to interpret the findings in terms of informing treatment options, in particular the study introduces a relatively novel psychological variable with regard to research in this area, that of psychological mindedness. In the current study psychological mindedness is considered in relation to dependence and in relation to benzodiazepine users willingness to consider treatment.

Hypotheses

Hypothesis 1:

- (a) Those individuals in receipt of long-term repeat prescriptions for benzodiazepine medication will show evidence of psychopathology, as measured by the Brief Symptom Inventory.

(b) Furthermore, psychopathology will predict benzodiazepine dependence, as measured by the Severity of Dependence Scale.

Hypothesis 2:

Those individuals in receipt of long-term repeat prescriptions for benzodiazepine medication will show evidence of poorer sleep quality, as measured by the Pittsburgh Sleep Quality Index.

Hypothesis 3:

Those individuals exhibiting poorer sleep quality, as measured by the Pittsburgh Sleep Quality Index, will have increased levels of psychopathology, as measured by the Brief Symptom Inventory.

Hypothesis 4:

Those individuals exhibiting greater dependence on benzodiazepine medication as assessed by the Severity of Dependence Scale will be less psychologically minded as assessed by the Psychological Mindedness Scale.

Chapter 7: Methodology

Design

Aim

The aim of the study was to establish whether a common psychological profile prevails among individuals in a primary care population who have been taking prescribed benzodiazepine medication for longer than the recommended period of time. The study included patients who were prescribed benzodiazepines by their general practitioners for either anxiety or sleep problems. Detailed information was gathered with regard to the psychopathology (including anxiety, depression, somatisation, phobic anxiety, inter-personal sensitivity, insomnia and benzodiazepine dependence) of this patient group.

It was anticipated that these data would be beneficial for two reasons. First, they would inform the psychological treatment of those individuals in the study, should they request help to stop using benzodiazepines. Second, these data could suggest alternative treatment options for future patients, that present to their general practitioners with difficulties that may lead to the repeat prescription of benzodiazepine medication.

Study design

The research design employed was a cross-sectional survey of an identified population using standardised questionnaires. The design therefore utilised between-subject measures to examine the relationships between subjects on a number of variables.

The purpose of the enquiry was to portray an informed psychological profile of this patient group.

The study involved administering a number of psychological questionnaires to each participant. The questionnaires that were used have well-established validity and have been widely used for both research purposes and in clinical practice.

Participants

In total, 84 participants took part in the study; Table 6 gives demographic details according to sex for age, employment status and whether participants lived alone or with another person.

Table 6: Characteristics of the sample: age, sex, employment and whether living alone

		Female (<i>N</i> = 56)	Male (<i>N</i> = 27)	
Age in years	Mean	73.03*	70.77*	
	SD	12.65	13.48	
	Range	36–93	41–92	
				% of total sample
Employment Status	Employed	6	2	9.5
	Unemployed	7	7	16.7
	Retired	44	18	73.8
Living alone or with someone	Alone	31	7	45.8
	Not alone	25	20	54.2

(* No significant difference was found between the age of male and female participants.)

Measurements and Instruments

Semi-structured interview

A semi-structured interview was carried out with each participant. The purpose of the interview was to gather information from the participants about their history of benzodiazepine use, pattern of use and the factors that might have influenced their benzodiazepine use. The interview also provided an opportunity for the researcher to collect selected demographic details. (The interview schedule can be found in Appendix 2.)

Questions about the history of benzodiazepine use:

- “What was the original reason you were prescribed benzodiazepine medication?”
- “Can you remember who gave you your first prescription? *(If yes)* “Who?”
- “How long have you been in receipt of your prescription?”

Questions pertaining to a participant’s pattern of benzodiazepine use:

- “What is the current reason(s) for your use of benzodiazepine medication?” *(If the participant gave more than one reason they were asked to rate them)*
- “Do you take your tablets as prescribed by your doctor?” “For example is that everyday or just at certain times?” “If at certain times when would that be?”
- “Would you like to stop or reduce your BZD tablets?” *(If yes)* “What help do you think you would need?” “For example who do you think could help?” *(If no)* “What are your reasons for not wanting to change your current use of BZD?”

Questions pertaining to factors that might have influenced a participant’s benzodiazepine use or demonstrate a dependence on another substance:

- “Do you have any medical health problems?” (*If yes*) “Are you taking any medication?”
- Do you have any painful conditions? (*If yes*) “What?” “How long?” “Pain relief?”
- “Do you drink alcohol?” (*If yes*) “How much?” “For example what would you drink in an average week?” “If you drank more alcohol in the past was it ever a problem?” “For example do you think you ever drank too much?”
- “Do you smoke cigarettes?” (*If yes*) “How many?” “How long have you smoked?” “If you smoked in the past, when and why did you stop?” “How long did you smoke for?”

Demographic information:

Information elicited from the participant during the interview included employment status and marital status. If a participant was not working they were asked how long they had not been in work or had been retired. If a participant lived alone they were asked how long this had been the case.

The remaining demographic details were collected from the practice GPASS¹ database.

These included:

- Sex
- Date of birth
- The length of time the participant had been in receipt of their benzodiazepine prescription.
- The type of benzodiazepine medication and the prescribed dose (this might differ from actual dose consumption reported in the semi-structured interview).

Finally, at the end of the semi-structured interview participants were asked if they would like to stop or reduce their use of benzodiazepine medication. If they said that they would like to change their benzodiazepine use they were asked what help they thought they would need to



make this change. If they answered that they did not want to change their benzodiazepine use, they were asked for their reasons for this decision. Participants were also asked if they had anything else that they would like to add, or if they felt that the researcher should have asked them anything else.

Questionnaire measures

Four questionnaires were selected for the study. The rationale behind the selection of each questionnaire and a description of each questionnaire is given below. (A copy of the combined questionnaire can be found in Appendix 2)

The Severity of Dependence Scale (SDS)

The SDS was devised by Gossop et al (1995) to provide a short and easy to administer self-report questionnaire with which to measure dependence for different types of drugs. The SDS items are explicitly concerned with psychological components of dependence, with no reference made to physical symptomatology such as withdrawal symptoms. Ballie (1996) has argued that relying on withdrawal symptoms, as an indicator of dependence is not adequate. The items in the SDS are intended to examine an individuals control over their drug use and their preoccupation and anxieties about their drug use.

The SDS was adapted by De Las Cuevas et al (2000) for use as a screening instrument for benzodiazepine dependence. Quite simply the word “drug” in the original SDS was substituted with the word “tranquilliser”.

¹ GPASS - The General Practitioner Administration System for Scotland was established in 1984, using software originally developed by a Glasgow GP. GPASS is a national computerised Primary Care system and is now used in over 84% of general practices in Scotland.

The SDS validation study (De Las Cuevas et al 2000) suggests a cut-off score of >7 to indicate benzodiazepine dependence. This cut-off score predicts overall sensitivity of 97.9 per cent and specificity of 94.2 per cent. However, this finding was based upon a validation study, which used a sample drawn from attendees of a mental health outpatient service. Therefore, the cut-off score of >7 may not be definitive when the SDS is used with other client groups.

The authors of the SDS validation study propose that the adapted form is an “extremely” useful scale with the following uses:

- In surveys requiring a screening test for benzodiazepine dependence.
- A measure of the severity of benzodiazepine dependence.
- For use as a quantitative measure to examine the correlation with other measures.
- For use as an indicator of the prevalence of benzodiazepine dependence.

The SDS was particularly suitable for use in the current study because of its brevity. A more comprehensive measure such as The Benzodiazepine Dependence Questionnaire (Baillie 1996) was considered but was felt to be too long for the purpose of the current study. The length of the SDS questionnaire was an important consideration because it was to be combined with three other questionnaires.

Structure: The SDS comprises five items, each with a choice of four responses. The items are scored on a four-point scale (0–3) producing a total score with a range from 0–15, with higher scores indicating greater severity. The referent time-period provided to the respondent is “during the last month”. (The SDS items can be located in the combined questionnaire in Appendix 2 labelled “Severity of Dependence Scale”)

The Brief Symptom Inventory (BSI)

The BSI is a subset of the Symptom Checklist-90-R (SCL-90-R) and was devised by Derogatis in 1975. The instrument assesses a broad range of psychological problems and symptoms of psychopathology, including symptom intensity. The BSI has been used in mental health, medical and educational settings as well as for research purposes. It is effective in the initial evaluation of patients as well as for monitoring progress and treatment outcome.

The BSI comprises nine symptom dimensions, but for the purpose of the current study only five of the dimensions were used. The decision to exclude four dimensions arose because they assessed extraneous symptomatology as far as the requirements of the current study.

Excluded dimensions

Obsessive Compulsive Disorder OCD – This has a relatively low prevalence rate in older adults of whom the current subject sample mostly comprised. Therefore, it was reasonable to predict that this dimension would be the least useful of the three “anxiety” dimensions included in the complete BSI. In addition, the author felt that some of the six items that comprise this dimension were not specific to OCD, particularly in the current cohort, and may not simply assess OCD but also other difficulties. Examples of two such items include “Trouble remembering things” and “Trouble concentrating”.

Hostility – According to the authors of the BSI, the hostility items were devised to assess anger and included items such as “Having urges to beat, injure or harm someone” and “Having urges to break or smash things”. Because “anger” does not represent a psychiatric disorder, this dimension was not included in the current study.

Paranoid Ideation and Psychoticism – Clinical judgement was brought to bear in the decision not to include paranoid ideation and psychoticism items in the current study. The author felt that it would be unlikely that participants from a primary care cohort would endorse such

items and may find them off-putting. Potential participants with a diagnosis of dementia or psychotic illness had already been excluded from the study.

Dimensions of the BSI selected for the current study

The definitions given by Derogatis (1975) for each of the five dimensions selected from the BSI are reproduced in Table 7 below:

Table 7: Description of five BSI dimensions

Somatisation	“The somatisation dimension reflects distress arising from perceptions of bodily dysfunction. Items focus on cardiovascular, gastrointestinal and respiratory complaints; other systems with strong autonomic medication are included as well. Pain and discomfort of the gross musculature and additional somatic equivalents of anxiety are also components of somatisation.”
Interpersonal Sensitivity*	“The interpersonal sensitivity dimension centres on feelings of personal inadequacy and inferiority, particularly in comparison with others. Self-deprecation, self-doubt and marked discomfort during interpersonal interactions are characteristic manifestations of this syndrome.”
Depression	“The symptoms of the depression dimension reflect a representative range of the indications of clinical depression. Symptoms of dysphoric mood and affect are represented as are lack of motivation and loss of interest in life.”
Anxiety	“General signs such as nervousness and tension are included in the anxiety dimension, as are panic attacks and feelings of terror. Cognitive components involving feelings of apprehension and some somatic correlates of anxiety are also included as dimensional components.”
Phobic Anxiety	“Phobic anxiety is defined as a persistent fear response to a specific person, place, object or situation that is irrational and disproportionate to the stimulus and leads to avoidance or escape behaviour. The items of this dimension focus on the more pathognomic and disruptive manifestations of phobic behaviour.”

* As with the hostility dimension, interpersonal sensitivity is not regarded as a psychiatric disorder. However interpersonal sensitivity was included because it was felt that as a concept it was closely linked to anxiety, particularly social anxiety, and could be endorsed by those individuals that were found to be anxious.

The BSI also has the added advantage that normative scores have been developed for its use with adults aged 60 years and over. Male and female normative scores on the BSI were

published by Hale et al (1984) derived from a large sample ($N = 565$) that had a mean age of 73 years.

Structure: The number of questions for each of the five selected dimensions of the BSI are as follows (total 28 questions): Depression six questions; Anxiety six questions; Phobic Anxiety five questions; Somatisation seven questions; Interpersonal Sensitivity four questions. Respondents were required to indicate their experience of each symptom on a five-point scale of increasing severity from “not at all” to “extremely”. A mean score for each dimension is derived from each set of raw scores. The referent time-period provided to the respondent is “during the past 7 days including today”. (The BSI items can be located in the combined questionnaire in Appendix 2 labelled “Brief Symptom Inventory”)

The Pittsburgh Sleep Quality Index (PSQI)

The PSQI (Buysse et al 1989) is a comprehensive self-report sleep questionnaire designed to assess areas such as sleep latency, sleep efficiency, daytime dysfunction and overall sleep quality.

In considering the applications of the PSQI, the authors state that it can be used to study...

“...the relationship between sleep quality and other variables, such as age, gender, health status, medical and psychiatric conditions, and performance on other psychological variables.” (p.207). The authors of the PSQI recommend a global PSQI score of greater than 5 to distinguish “poor” sleepers from “good” sleepers. This cut-off was found to yield a sensitivity of 89.6 per cent and specificity of 86.5 per cent.

The PSQI is used to assess sleep quality over a 1-month interval. The questionnaire comprises 19 items; however, for the purpose of the current study, item 19 was excluded because it consists of questions for clinical information only which are not tabulated in the scoring of the PSQI.

Structure: With the exception of the first four items the PSQI questions utilise forced-choice responses on a four-point scale of increasing severity. The 18 self-rated items are combined to form seven “component” scores which are allocated a score with a range of 0–3: subjective sleep quality; sleep latency; sleep duration; habitual sleep efficiency; sleep disturbances; use of sleep medication; daytime dysfunction. The seven component scores are added together to yield a global score, with a range of 0–21. Higher scores indicate severity of sleep problem. (The PSQI items can be located in the combined questionnaire in Appendix 2 labelled “Pittsburgh Sleep Quality Index”)

The Psychological Mindedness Scale (PMS)

The PMS was chosen because the questionnaire items appeared to be relatively easy to understand and more applicable to the proposed sample, than questionnaire items in the other psychological mindedness questionnaires. However, the author was unable to locate any published research that had used the PMS in any studies similar to the current study, its suitability in the current setting was therefore untested.

In an examination of the factor structure of the PMS, Conte et al (1996) found five principle factors, which were labelled as follows:

- Willingness to try to understand oneself and others
- Openness to new ideas and capacity for change
- Access to one’s feelings
- Belief in the benefits of discussing one’s problems
- Interest in meaning and motivation of own and others behaviour

Although only 27 of the 45 items account for this factor structure the authors did not shorten the scale, arguing that the remaining items still contributed to the scale.

Structure: The PMS comprises 45 statements to which the respondent rates their strength of agreement or disagreement. The statements are worded both positively and negatively and are answered by means of a four-point Likert scale. The scale generates a total score that can be converted to a percentile rank. (The PMS items can be located in the combined questionnaire in Appendix 2 labelled “Psychological Mindedness Scale”)

The four questionnaires were combined to give appearance of one long questionnaire. With the exception of the first four PSQI items, all items offered closed fixed-alternative responses that required the respondent to place a tick in the corresponding box. Print was enlarged as much as space would allow to assist respondents with poor eyesight. Questionnaires were not counterbalanced (see discussion of order effects below).

Pilot study

The pilot study described in Appendix 2, involved collecting qualitative and audit data which was used to inform the design of the main study. Without the pilot study it would have been difficult to decide upon which measures to use in the main study. For example, the pilot study revealed that the predominant reason for benzodiazepine use in the target subject population was because of sleep difficulties. This prompted the selection of an appropriate measure to assess sleep quality.

The pilot study found that the majority of potential participants were aged over 65 years. This gave rise to the consideration of questionnaire factors such as comprehensibility and length, because many older adults may have been less familiar with the process of completing questionnaires. It was also important to check whether a potential questionnaire was restricted to particular age groups.

The participants in the pilot study were found to be resistant to any suggestion that they might be dependent or addicted to their benzodiazepine medication. Therefore, the

questionnaire measure of dependency for the main study was carefully selected, avoiding the use of such words.

The pilot study also highlighted the requirement for the researcher to be available to visit participants in their own homes, as many of the potential participants were quite elderly and would have mobility or transport difficulties. The need to visit participants in their own homes would require more time and this was allowed for when planning the time-scale of the main study.

Power calculation

The author located a paper by Marsden et al (2000) which used multiple regression analysis to examine the predictors of psychiatric symptoms. The study used both the SDS and the BSI, along with other variables. However, in contrast to the present study Marsden et al sought to establish predictors of psychiatric symptoms, as measured by the BSI, therefore BSI scores formed the dependent variable and SDS score was one of the independent variables. The current study aimed to examine whether psychopathology (using the BSI) predicted severity of dependence (SDS).

Using Cohen's (1992) formula for calculating effect size (for multiple regression analysis), the Marsden et al study was found to demonstrate a large effect size ($d = 0.58$). This was not surprising when one considered the heterogeneous features of the study cohort, which were drawn from a range of community and residential settings. The present study would consist of a more homogeneous group of participants (compared with the Marsden et al study), therefore, it would be prudent to select a more conservative effect size. A medium effect size was selected. Based on Cohen's (1992) estimate of sample size (setting power at 0.8 and alpha at 0.05) multiple regression analysis would require that $N = 91$ (for five independent variables).

For correlational analysis and testing differences between two independent means, assuming medium effect size (setting power at 0.8 and alpha at 0.05), $N = 85$ and $N = 64$ respectively. Therefore, recruitment of 91 subjects would provide a reasonable chance of rejecting the null hypothesis and allow testing of sub-hypotheses using correlational and t-test analyses.

Ethical approval

Ethical approval was sought from the Borders Research Ethics Committee (BREC) and granted without any amendments requested. A copy of the BREC approval can be found in Appendix 3.

Procedure

Data collection consisted of three stages. Stage one involved postal recruitment of potential participants by general practitioners. Stage two involved follow-up postal or telephone contact with potential participants by the researcher to arrange the interviews. Stage three consisted of data collection, which involved a single face-to-face contact with each participant. This process was carried out over a four-month period.

Recruitment of participants

The study was carried out in the Scottish Borders. Eighty three per cent of the participants recruited for the study were recruited from one general practice. Although the study was originally planned to focus on one general practice, because of the shortfall in participants required for the study (based on the original power calculation) a second smaller general practice, also in the Scottish Borders, was approached and agreed to participate. Both

general practices are situated in rural communities, geographically 15 miles apart. They could be considered similar in terms of socio-economic status.

The first stage of the recruitment process involved each general practitioner contacting all their registered patients who were in receipt of a repeat prescription for benzodiazepine medication for more than three months. This included all adult patients (over 18 years) who were prescribed one of the following: temazepam, diazepam and nitrazepam.

This information was collected using a GPASS database search. The search results were grouped according to individual general practitioners so that a patient list could be circulated to each doctor. The general practitioners were asked to consider each patient on their own list for their suitability to participate in the study. The exclusions that the general practitioners were asked to screen out are given below.

Exclusion Criteria

The study was not concerned with people taking benzodiazepines obtained from an illicit source (i.e. black-market use of benzodiazepines). In addition, the study did not include patients prescribed benzodiazepines for alcohol withdrawal, epilepsy or psychiatric conditions such as dementia and psychotic illness. Persons with a learning disability were also excluded.

The total number of potential participants following the application of the exclusion criteria was 161.

A letter to patients was composed by the general practitioners collectively, it contained information introducing the proposed study and requested that they consider taking part. The general practitioners were given guidelines by the author to ensure that certain essential points were made in the letter. For example, the general practitioners were advised that potential participants must be made aware that participation in the study would be anonymous and all information they disclosed to the researcher would be confidential. Each

general practitioner signed the letter sent to their own patients. A copy of the letter can be found in Appendix 4.

Potential participants were asked to return the slip enclosed with the letter in the stamped envelope addressed to their own general practitioner. The return slip requested that the potential participant indicate a response to two questions. Firstly, the respondent was asked if they would be willing to be contacted by the researcher about the study: (i) yes or (ii) no. This question was qualified by the following statement: "Note: ticking yes does not mean that you are agreeing to take part, just that you are willing to be approached." Secondly, the respondent was asked whether they would be happy to be contacted by (i) letter or telephone or (ii) just by letter.

Returned slips that indicated that the potential participant would be willing to be contacted about the study were forwarded to the author.

The second stage of the recruitment process was executed once a potential participant had given their permission to be approached by the author. The majority (77 per cent) of respondents ticked the box on their return slip indicating that they did not mind whether they were contacted by telephone or by letter. The author telephoned all these individuals and explained to each of them further details of the study. They were then asked if they would be happy to participate and if they agreed a convenient time was arranged.

Contacting potential participants by telephone at this stage proved to be a more successful method than by postal letter. Of the 70 individuals that were telephoned and asked to participate 66 agreed.

Those individuals that returned their slip indicating that they agreed to be contacted about the study but would prefer to be contacted by letter were sent another letter (see Appendix 4). This second letter gave the potential participant further information about the study and included another return slip which offered a choice of three appointment times and the choice of venue (local health centre or home). The respondent was asked to complete the slip and return it in the stamped addressed envelope provided. Of the 21 individuals that were

contacted a second time by letter, 18 returned their slip having selected an appointment time. Unlike the larger group of participants that were contacted by telephone, most of this group chose to come into the health centre to be seen.

The decision to contact potential participants by telephone was made for two reasons. Firstly, this method was quicker and cheaper. Secondly, it was felt that having a conversation with a potential participant provided a better opportunity to explain to the potential participant what would be involved if they agreed to participate in the study and address any concerns they might have.

Table 8: Summary of response statistics:

Return slip ticked yes = agreed to be contacted				Return slip ticked no = did not wish to be contacted	Return slip not returned
N = 91				N = 24	N = 46
Requested contact by telephone or letter		Requested contact by letter but not telephone			
N = 70		N = 21			
Agreed to participate	Did not wish to be seen	Agreed to participate	Did not wish to be seen		
N = 66	N = 4	N = 18	N = 3		
Home visit	Health centre	Home visit	Health centre		
N = 62	N = 4	N = 7	N = 11		

Of the 161 patients (across the two GP practices) that were contacted to participate in the study 52 per cent took part in the study.

Data collection

Data collection involved a single meeting with each participant, usually in their own home.

(Eighty two per cent of participants agreed to be seen in their own home and 18 per cent of

participants requested to be seen at the health centre.) The semi-structured interview was carried out first, using a prepared interview schedule. This was followed by the administration of the questionnaire.

Interview procedure

The researcher began by reiterating the information contained in the introductory letter used to recruit participants for the study. The purpose of the research was explained to each participant and each was reassured of complete confidentiality and the respect for anonymity.

The researcher then outlined how the interview would proceed, i.e. a brief “chat” about the participants use of benzodiazepine medication, followed by the completion of a questionnaire. Once the researcher had elicited from the participant that they were happy to proceed they were asked to sign two copies of a consent form. The researcher kept one copy and the participant kept the other copy.

The interview schedule was adhered to with each participant, thus providing some consistency in terms of the order in which the questions were asked. Some participants volunteered a lot of additional information; therefore completion of the interview took a variable amount of time.

The inclusion of open-ended questions in the semi-structured interview allowed an opportunity for rapport-building with the participant, because these types of questions allowed greater freedom for the participant to talk about what was relevant to them. Whilst much of the information reported in response to an open-ended question was not relevant to the research questions, it afforded an opportunity for the participant to express their point of view. This reciprocal aspect of the interaction between researcher and participant can benefit rapport.

Administering the questionnaire

The interviewer remained with the participant during completion of the questionnaire, to clarify any confusion surrounding how to fill in the questionnaire or interpret the questions.

The majority of the participants requested that the researcher filled in the questionnaire with them. In theory, the questionnaire should have been relatively easy to complete because the process merely involved ticking a choice of boxes. However, many of the more elderly participants were found to deliberate over the alternative choices and required a prompt to select a response. The last section of the questionnaire, which consisted of the psychological mindedness questions, proved to be the most difficult and time-consuming to answer.

Younger participants were found to complete the questionnaire more easily; one could speculate that older adults are less familiar with answering questionnaires and they appeared to be more worried about making sure they “got it right”.

Many participants commented on the repetition found in the psychological mindedness questionnaire.

At the end of the meeting, participants were thanked for their participation and given an information leaflet about benzodiazepine medication. It was explained to each participant that should they decide that they would like to stop taking benzodiazepine medication they would be given help to do this involving both their general practitioner and the author. It was emphasised to them that they should not stop their medication without first consulting their general practitioner (this advice is also stated clearly on the leaflet). The leaflet contained a return slip that could be handed in to the health centre by the participant, indicating that they wished to be contacted about stopping their benzodiazepine medication.

Interviewing participants in their own home was considered preferable to the health centre because the home environment is generally considered less anxiety provoking. The home environment was also found to contribute to rapport building, for example participants

visited in their own homes frequently offered the researcher tea/coffee and engaged in general “chit-chat” before and after the interview. In addition, when an appointment was arranged with a participant to be seen in their own home there was more likelihood that the participant would attend.

Order effects

The decision to proceed first with the interview followed by the questionnaire is supported by evidence that indicates that a questionnaire, by virtue of its structured questions, can become a “learning exercise”, thus creating an agenda for the participant, which can spill over into the subsequent interview and influence their discourse (Best et al 1995). It also made sense in this study to begin with the semi-structured interview, as the first few questions elicited demographic information that a participant would expect to be asked of them first. The open-ended interview questions provide an opportunity to build rapport with the participant.

Although the questionnaire was presented as a single questionnaire with all questions following on continuous pages, it consisted of four distinct questionnaires, thereby creating the potential for order effects. However, because each questionnaire focused on different topics, which bore very little relation to each other, the author felt the potential for “cueing” across the questionnaire items was low. For example, it seemed unlikely that answering questions about sleep quality before answering questions about psychiatric symptomatology would influence how the questions about psychiatric symptoms were answered. Therefore, the order in which the four questionnaires were presented was not counterbalanced.

The four questionnaires were presented as one questionnaire in the following order:

- (i) Pittsburgh Sleep Quality Index
- (ii) Brief Symptom Index

(iii) Severity of Addiction Scale

(iv) Psychological Mindedness Scale

The sleep quality questions were placed first because sleep problems were the most salient issue for the majority of participants. Therefore, questions about sleep met with the participant's expectation and could be viewed as easing the participant into the questionnaire. The psychological mindedness questions were placed at the end of the questionnaire, because they were the most difficult to answer and could be viewed as somewhat discouraging.

Preparing raw data for analysis

The questionnaire was divided into its four composite questionnaires and each was scored according to its own scoring mechanism. Information collected from the semi-structured interview was collated to form a large number of additional variables. Information pertaining to medical health problems and reasons for benzodiazepine use were categorised as described below. All benzodiazepine dosages were expressed in terms of diazepam equivalents using British National Formulary (BNF) conversion tables (2002) for use in statistical analysis. Diazepam equivalent doses were calculated as follows: 5 mg of diazepam is equivalent to 5 mg of nitrazepam and 10 mg of temazepam.

Reasons for benzodiazepine use

Participants gave a total of 10 different reasons for their original or current use of benzodiazepines. These data were therefore assigned to one of the 10 alternative categories (if during data collection a participant gave more than one answer in response to these two questions, they were asked to select the primary reason).

Medical conditions

Almost every participant in the study had one or more medical conditions for which they were prescribed medication. It therefore seemed that the most manageable way of categorising participants' medical health problems was to allocate each participant to one or more categories according to their medication. A record was collected of the repeat prescription issued to every participant.

The BNF groups all medications according to the condition they are used to treat; this system comprises 11 main categories of health problems. Each participant's medication was recorded according to these categories. Eight of the 11 BNF health categories were relevant to the participants' in the study; cardiovascular; gastro-intestinal; central nervous system; respiratory system; musculoskeletal; endocrine system; malignant disease and immunosuppression; obstetrics, gynaecology and urinary tract disorders. Recording these data in this way allowed for the prevalence for each medical category to be calculated and gave rise to a total number of medical categories per participant. However, it is noted that this method affords only a crude system of recording the medical health problems of the current sample.

All data were entered in to SPSS (Statistical Package for the Social Sciences) version 10.

Chapter 8: Results

Preparation of data for analysis

Requirements for parametric tests: The distributional assumptions of the variables to be analysed using parametric statistics were considered. The five BSI variables were found to be positively skewed and therefore a natural logarithm ($x+1$) transformation was carried out on each variable. The distribution of total scores for the remaining three measures (PSQI, PMS, SDS) did not depart significantly from normality. Additional dichotomous and ordinal variables were analysed using nonparametric tests. Data was analysed using SPSS (Statistical Package for the Social Sciences) version 10. The significance level of test results, unless otherwise stated, was set at $p = .05$ (two-tailed).

Descriptive statistics: characteristics of the sample

The information gathered by means of the semi-structured interview was collated and is presented descriptively below. A number of these variables were analysed further using inferential statistics.

Prevalence rate

Using GPASS data for the first practice from which participants were recruited for the study, the following prevalence rates were calculated. In the total practice population of adults over 18 ($N = 4857$) the number of patients in receipt of a long-term repeat prescription for benzodiazepine medication was found to be 136; this amounted to a total practice prevalence rate of 2.8 per cent.

Prevalence rates according to age and sex were computed: 3.1 per cent of males ≥ 60 years; 9.4 per cent of females ≥ 60 years; 0.9 per cent of males under 60 years; 1.1 per cent of females under 60 years.

Type of benzodiazepine used: dosage and number of years taken

Across all benzodiazepines the mean number of years that participants had been in receipt of their benzodiazepine medication was 10.8 (SD 8.19) years, the modal number of years was 20.

Table 9 below shows the mean daily dose for each benzodiazepine and the BNF (British National Formulary 2002) recommended doses for “elderly” patients. The table also includes the mean number of years each benzodiazepine was prescribed.

Table 9: Dose and length of time in receipt of benzodiazepines

Type of BZD	N (%)	Mean dosage (SD)	BNF Recommended dose	Mean years in receipt of BZD* (SD)
Diazepam	20 (28.80)	5.40 mg (3.83)	7.5 - 15 mg	10.95 (8.05)
Temazepam	37 (44.04)	14.59 mg (11.86)	10 mg	8.56 (6.39)
Nitrazepam	27 (32.14)	5.78 mg (3.38)	2.5 - 5 mg	13.88 (9.66)

*A significant difference was found between the mean number of years in receipt of BZD across type; ($F(2,81) = 3.498$; $p = 0.035$). Post hoc analysis revealed that participants in receipt of nitrazepam had been taking it significantly longer than participants who were in receipt of temazepam.

Length of time in receipt of benzodiazepine medication and association with age

Participants were grouped into three age groups: adult (<60 years); young older adults (60-69 years); old older adults (70+ years).

Distribution of participants across the three groups was as follows: Adults – $N = 16$, mean age 51.7 (SD 6.39); Young older adults – $N = 16$, mean age 65.6 (SD 3.3); Old older adults – $N = 52$, mean age 80.6 (SD 5.9).

Figure 3 below shows the mean age at which benzodiazepines were commenced and mean number of years participants were in receipt of benzodiazepines according to age group. The graph illustrates that on average the older group (over seventy years) and young old (sixty to seventy years) have been taking their benzodiazepines for a similar period of time. This suggests that older age does not necessarily mean that benzodiazepines have been used for a longer period of time. In addition, no statistical relationship was observed between *age* and the *length of time* in receipt of a benzodiazepine.

Pearson’s correlational analysis demonstrated that there was a significant positive correlation between *age* and *age when commenced* benzodiazepine ($r = .816, p = <0.001, n = 84$). This would suggest that older adults are as likely to be commenced on benzodiazepine medication as younger adults.

Figure 3: Graph to show mean age at which BZD were commenced and mean number of years in receipt of BZD according to age group

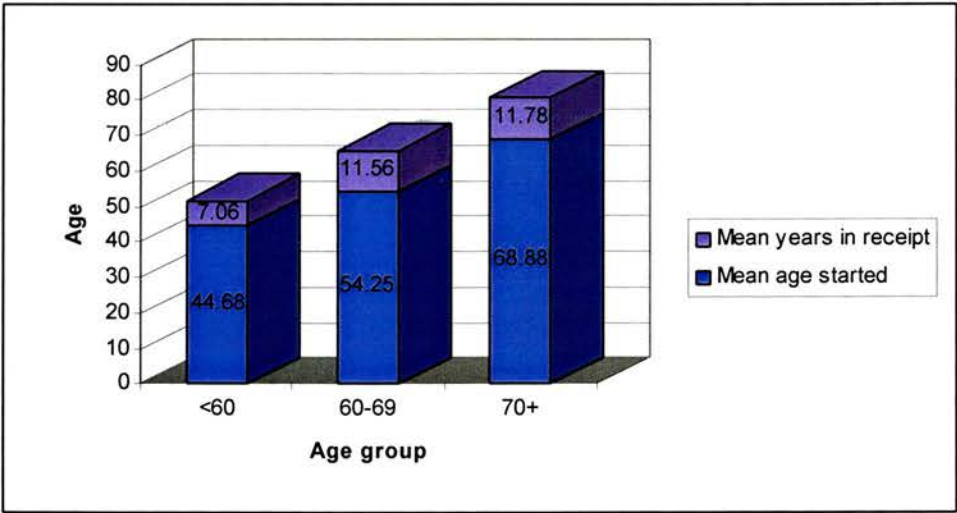
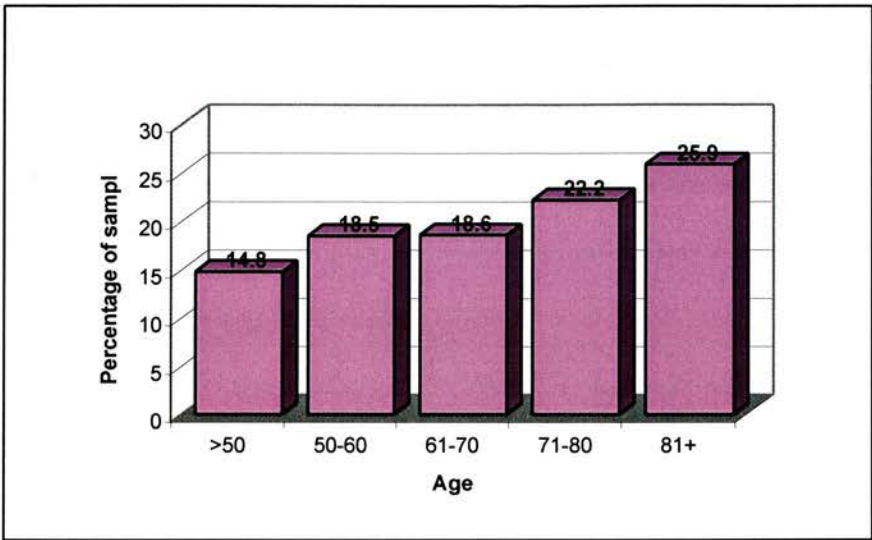


Figure 4 below shows that of those patients commenced on a benzodiazepine in the last 5 years nearly 50 per cent were over 70 years old.

Figure 4: Age distribution of patients who commenced benzodiazepine in last 5 years



Is there a relationship between living alone and benzodiazepine use

Of the 84 participants, 39 participants lived alone. The mean number of years lived alone was 12.6 years (SD 12.6) after one outlier was removed from the calculation. These 38 participants were all widowed.

A significant positive correlation was found between the *number of years in receipt* of benzodiazepines and the *number of years lived alone* ($r = .483, p = 0.002, N = 38$). When this relationship was explored further, it was found that the significant relationship between the *number of years in receipt* of benzodiazepines and the *number of years lived alone* was only significant for the thirteen participants who commenced benzodiazepines following a bereavement ($r = .871, p = <0.001, N = 13$). Therefore, with the exception of individuals

commenced on benzodiazepines as a result of bereavement, there does not appear to be an association between living alone and benzodiazepine use.

Medical conditions and benzodiazepine use

Eighty-three out of 84 participants were in receipt of a repeat prescription for medication(s) for a comorbid physical medical condition, in addition to their benzodiazepine. (See Appendix 5(a) for medical conditions)

Using Spearman's rank correlation analyses no significant association was found between *the number of health problems and sex, age, anxiety, depression, inter personal sensitivity, phobic anxiety, SDS score, and PQSI score.*

A significant association was found between increased *number of health conditions* and higher *somatisation* scores ($r = .240, p = 0.028, N = 84$).

Pain

The presence or absence of *painful conditions* and use of prescribed *pain relief* medication were correlated with *PSQI* score using a Point-biserial correlation. The presence of painful conditions ($r_{pb} = .344, p = 0.002, N = 81$) and use of prescribed pain relief ($r_{pb} = 0.340, p = .002, N = 81$) were associated with increased sleep disturbance. Participants formed two groups; participants that experienced pain ($N = 45$) and participants who did not experience pain ($N = 36$). Analyses found that there were significantly higher *PSQI* score ($t = 3.164, df = 79, p = 0.002$), and significantly larger dose of benzodiazepines used ($t = 2.294, df = 79, p = 0.024$) in the group who experienced pain, compared with the group who did not experience pain.

In addition, the group who experience pain were significantly more likely to use benzodiazepines daily ($z = 3.109, p = 0.002$).

Use of pain relief was associated with two categories of medical problem: musculoskeletal ($X^2 = 6.431, df = 1, p = 0.011$) and gastro-intestinal ($X^2 = 5.063, df = 1, p = 0.024$). Participants with these two types of conditions used significantly more pain relief.

Do participants wish to stop their benzodiazepine medication

Seventy-four percent of the total sample said that they **did not** wish to stop their benzodiazepine medication. Table 10 below shows that female participants were less willing to consider stopping their benzodiazepine medication than males. This difference was found to be statistically significant using chi-square analysis ($X^2 = 12.220, df = 1, p = <0.001$).

Table 10: Crosstabulation of sex and desire to stop benzodiazepine medication

			would like to stop bzd		Total
			like to stop	no	
SEX	male	Count	13	13	26
		% within SEX	50.0%	50.0%	100.0%
	female	Count	8	49	57
		% within SEX	14.0%	86.0%	100.0%
Total	Count	21	62	83	
	% within SEX	25.3%	74.7%	100.0%	

In addition, participants who use benzodiazepines less frequently were found to be more likely to consider stopping them ($X^2 = 12.157, df = 1, p = <0.001$).

Reasons given for benzodiazepine use

With the exception of participants who gave “anxiety” ($N = 6$) as their reason for commencing benzodiazepine medication, “problem sleeping” was the primary reason given.

Bereavement ($N = 13$) and stress and worry ($N = 12$) were the most commonly reported reasons for sleep problems leading to commencement of benzodiazepine medication. (See Appendix 5(b) for a more detailed examination of the reasons given for benzodiazepine use.)

Table 11 below cross-tabulates the original reason given by participants for commencing benzodiazepines with the current reason for taking benzodiazepines. These data demonstrate that a large number of patients continue to use benzodiazepines for sleep, despite the original reason for their sleep problem being no longer valid.

A surprisingly large proportion of the sample (38 per cent) could not identify a reason for their original presentation to their general practitioner with a sleep problem.

Seventy six per cent of the sample reported that their continued use of benzodiazepines was due to sleep problems for which they were unable to identify a reason.

Table 11: Cross-tabulation table for current and original reason for BZD use

Original reason	Current reason									
	Sleep	Stress & worry	Bereavement	Shift work	Pain	Depression	Muscle spasms	Tinnitus	Anxiety disorder	Total OR*
Sleep	32									32
Stress & worry	9	3								12
Bereavement	13									13
Shift work	2			1						3
Pain	2				6					8
Depression	3									3
Muscle spasms							4			4
Tinnitus								2		2
Anxiety disorder	2				1				3	6
Medical condition	1									1
Total CR*	64	3	0	1	7	0	4	2	3	84

*Total OR = total number for each original reason

*Total CR = total number for each current reason

Severity of Dependence Scale

The SDS questionnaire comprises five items, which require a response on a 4-point Likert scale. As shown in Figure 5 below the first four items utilise the same Likert scale. SDS item five (see Figure 6) has a different choice of responses.

Responses to SDS items 1–4 are positively skewed, although some more so than others. Response to the first SDS item “Did you think your use of tranquillisers was out of control?” (SDS1) demonstrate poor discrimination; responses to this question were very positively skewed. The distribution of responses across item 3 “Did you worry about your use of

tranquillisers?" (SDS3) were also found to be very skewed. Items 2, 4, and 5 appear to give rise to a more useful range of responses.

Figure 5: The distribution of responses to items 1–4 on the SDS

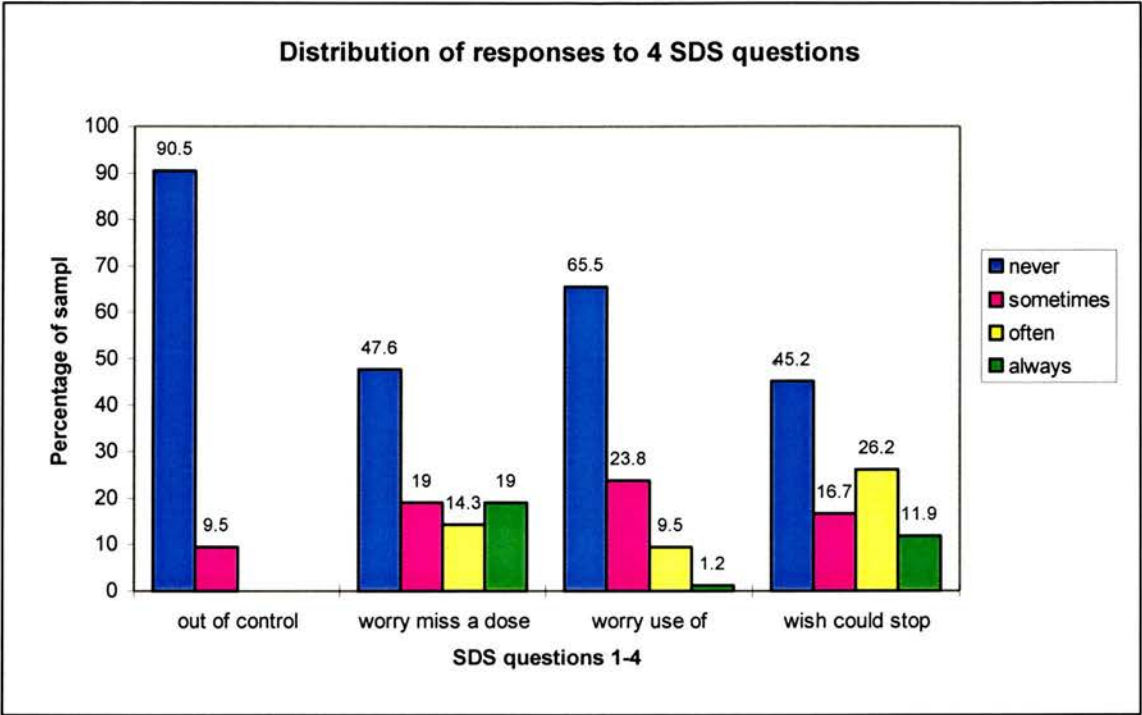
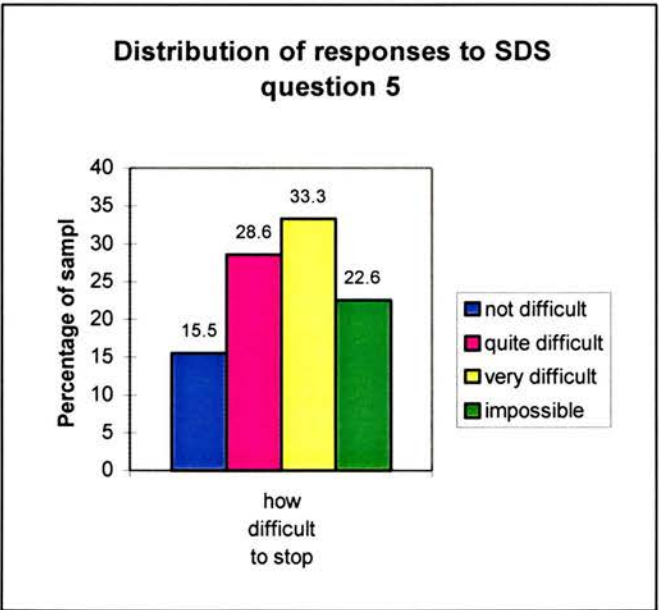


Figure 6: The distribution of responses to item 5 on the SDS



The relationship between the SDS items was explored using Spearman's rank correlation analyses (see Appendix 5(c) for the correlation matrix)

With the exception of three significant correlation coefficients, there were poor relationships between the five SDS items. The two items which appear to be most closely related were "How difficult would you find it to stop your tranquillisers?" (SDS5) and "Did the prospect of missing a dose make you anxious or worried?" (SDS2).

The results of the Cronbach alpha reliability analysis using covariance matrix found an alpha value of 0.299 (standardised item alpha: 0.335). This result compared unfavourably with the result of the reliability analysis reported in the SDS validation study by De La Cuevas et al (2000), which reported an alpha value of 0.813 (standardised alpha: 0.814).

During the semi-structured interview participants were asked about the frequency of their benzodiazepine use. This information was coded simply as "daily" or "not daily" usage. Sixty-one participants (72.6 per cent) used their benzodiazepine medication daily; 23 participants (27.4 per cent) did not use benzodiazepines daily. It was possible that frequency of benzodiazepine use might serve as a crude estimation of dependency, against which to evaluate responses to the SDS. The five SDS items and the SDS total score were correlated with *frequency of use* using Spearman's rank correlation analyses. A higher total SDS score ($r_s = .396, p = < 0.001, N = 84$); greater endorsement of "difficulty to stop" ($r_s = .460, p = < 0.001, N = 84$) and "worry about missing a dose" ($r_s = .389, p = < 0.001, N = 84$) correlated significantly with increased frequency of use.

To conclude, the five items comprising the SDS appear to lack internal consistency. Two SDS items "difficulty to stop" and "worry about missing a dose", seem to demonstrate a more valid measure of dependency, in the current sample, than the other items in the SDS.

The discriminative power of items 1 and 3 is low. This raises the question of the appropriateness of using the recommended cut off score.

An appropriate cut-off score for the SDS

The “cut-off” score as recommended by the authors of the SDS scale is: ≥ 7 . Using this cut-off with the current sample found that only 17.9 per cent of participants ($N = 15$) were classified as dependent on benzodiazepines. It seemed likely that this was an under estimation of dependence in the sample when one considered participants responses to SDS item 5 (Figure 6). For example, responses to SDS item 5 found that only 15.5 per cent of participants reported that they would **not** find it difficult to stop their benzodiazepines. A further 56 per cent of participants reported that they would find it either “very difficult” or “impossible” to stop their benzodiazepines.

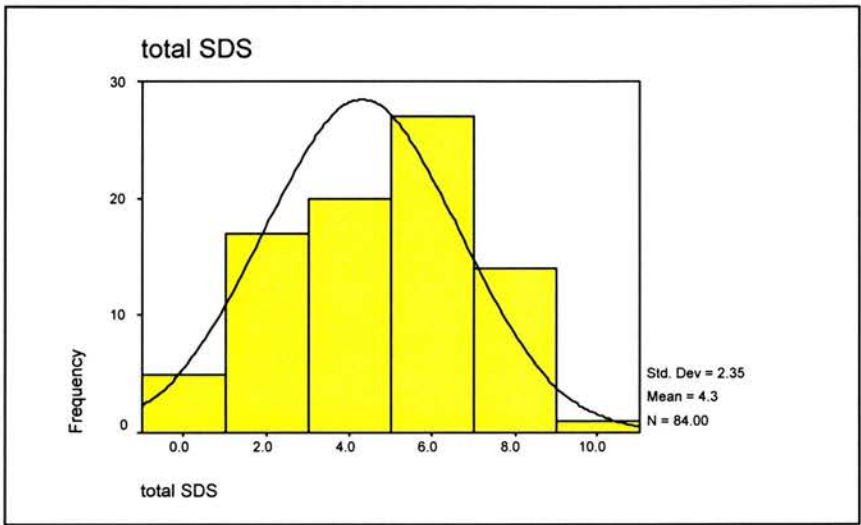
Closer examination of individual item scores highlights a pattern of responses which may explain the finding that 82.1 per cent of participants ($N = 69$) had a relatively low total SDS score. For example, 90.5 per cent of participants endorsed “never” in response to SDS item 1 “Did you think your use of tranquillisers was out of control”(Figure 5), thus scoring zero for this item. Participants were found to remark that because they took their benzodiazepine medication as prescribed by their general practitioner, they “believed” that their use of benzodiazepines “could not be out of control”. Similarly, for SDS item 3, 65.5 per cent of participants reported that they “never” worried about their use of benzodiazepines. Again participants attributed this response to their *prescribed* use of benzodiazepines.

It would therefore appear that because the individuals in the current sample were prescribed their medication by a general practitioner, this feature of the sample changed the relevance of these two SDS questionnaire items (SDS item 1 and SDS item 3). The author would argue that in the current sample SDS items 1 and 3 add very little to the measurement of benzodiazepine dependency. For example, the mean SDS total score ($N = 84$) derived from

the five SDS items was found to be 4.28 (SD 2.35). If SDS items 1 and 3 are excluded from this calculation the mean SDS total score ($N = 84$) derived from the remaining three SDS items is found to be 3.72 (SD 2.11), a difference of only 0.56.

To conclude, SDS items 1 and 3 make very little contribution to the total SDS score and it could be argued that in the current sample benzodiazepine dependency is more accurately measured by only three SDS items. Therefore, a cut off SDS score of 7 based on 5 items is not appropriate for a sample for whom only 3 items appear to be salient.

Figure 7: Frequency distribution of SDS total score



The proposed cut off score for dependence as measured by the SDS is normally 7, which is just below the half-way point on the potential scale of 0–15. As Figure 7 illustrates, SDS scores in the current sample range from 0–10, therefore, 4 represents just below the half-way point in this sample.

In order to decide upon an appropriate SDS cut-off score to measure dependency, a well-established method used in signal detection theory was employed (Green and Swets 1966). A Receiver Operating Characteristic (ROC) curve was generated to determine an optimum decision threshold (cut off point) using sensitivity and specificity values. The state variable

selected was *frequency of use*. Examination of the coordinates of the curve revealed that a cut off of 4 optimised sensitivity and specificity. The ROC graph and table coordinates of the curve can be found in Appendix 6(a).

The Pittsburgh Sleep Quality Index

The PSQI comprises 18 items that combine to form seven “component” scores, from which a global score is calculated. The mean global score for the total sample was found to be 11.07 (SD 4.05). The PSQI cut-off score (>5) proposes to distinguish between “poor” and “good” sleepers. In the current sample 90.5 per cent fell into the “poor sleepers” category.

Sleep latency represents the amount of time taken to fall asleep. The mean amount of time taken by participants to fall asleep was 38.1 minutes (SD 28.8). Mean sleep duration was found to be a total of 6.2 hours (SD 1.39) per night.

A greater sleep efficiency percentage represents more hours spent asleep whilst in bed. Mean sleep efficiency in the current sample was found to be a relatively poor 64.9 per cent (SD 16.02). The mean number of hours spent in bed by participants was found to be 9.08 hours (SD 1.70). Therefore, on average, participants appear to be spending one-third (about 3 hours) of their time in bed awake. (See Appendix 5(d) for details of PSQI component scores.)

Participants found to be dependent on benzodiazepines (using SDS cut off of 4) were found to have a significantly higher PSQI score than non dependent benzodiazepine users ($t = 3.839$, $df = 82$, $p = <0.001$). However, no difference in PQSI score was found between daily and non daily benzodiazepine users.

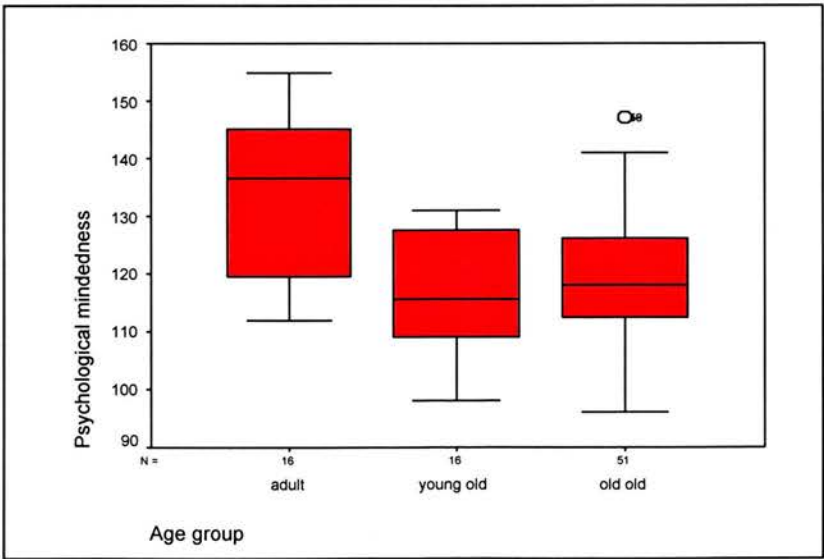
Psychological Mindedness Scale

The PMS questionnaire scores can range from ≤ 102 (percentile 0) to ≥ 170 (percentile 99). The mean PMS score in the current sample was found to be 121.4 (SD 13.34). The mean percentile score was 27.9 (SD 27.68). Psychological Mindedness in the current sample would therefore appear to be below average.

A small but statistically significant correlation was found between age and PMS score ($r = -.277, p = 0.011, N = 84$). This suggests that older persons are likely to be less psychologically minded. The PMS scores did not correlate with the following variables: *sex, dose of BZD, length of time in receipt of BZD, number of health conditions or pain.*

A significant difference was observed between PMS score according to age group ($F(2,81) = 9.818; p = <0.001$). Post hoc analysis revealed that adults were significantly more psychologically minded than “young” older adults and “old” older adults. There was no difference between PMS scores for “young” older adults and “old” older adults. Figure 8 illustrates the boxplots of the PMS scores according to age group (after removal of one extreme value).

Figure 8: Boxplots of PMS scores categorised by age group



Brief Symptom Inventory

The BSI dimensions each comprise between 7 and 4 questionnaire items, from which a mean score is derived. A larger mean represents more symptomatology.

Figure 9 below plots the mean scores for (i) male and female participants aged 60 years and over ($N = 68$) and (ii) normative scores for an elderly population (≥ 60). Figure 10 below plots the mean scores for (i) male and female participants aged below 60 years ($N = 16$) and (ii) normative scores for an adult population. It was not possible to plot the comparison between the sample mean and population means on a single graph because the BSI population norms vary across age group.

Mean BSI dimension scores appear to be higher for the second group of participants below 60 years (Figure 10).

Participants were divided in to two groups: under 60 years old and 60 years and above. No significant differences were found between the two groups on a number of variables: dosage, frequency of usage, individual medical health conditions and total number of health conditions, painful conditions, PSQI score and SDS score.

Figure 9: Graph to show comparison between sample mean scores and normative scores in participants 60+ years

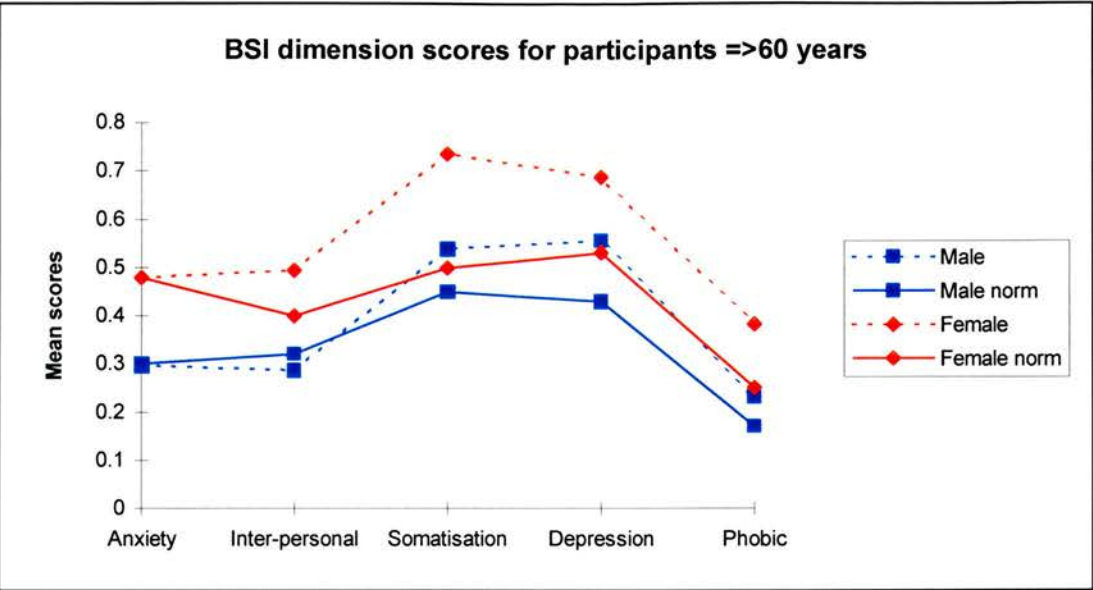
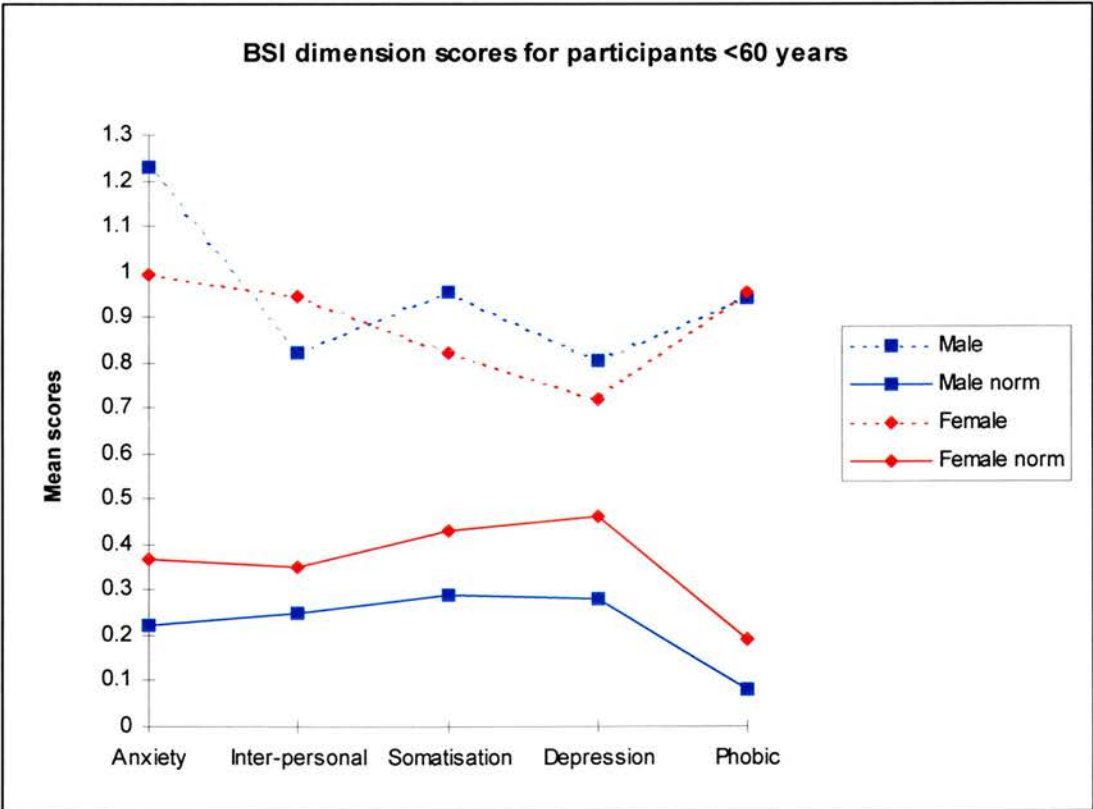


Figure 10: Graph to show comparison between sample mean scores and normative scores in participants less than 60 years



To explore the relationship between BSI dimension scores, age and sex a three-factor mixed factorial anova was computed ($N = 84$):

Three-factor mixed ANOVA	
Within-Subjects Effects	
BSI dimensions	- $F(4,80) = 2.269$; $p = .062$
Interaction between BSI dimensions X Age	- $F(4,80) = 3.825$; $p = 0.005$
Interaction between BSI dimensions X Sex	- $F(4,80) = .711$; $p = 0.585$
Interaction between BSI dimensions X Age X Sex	- $F(4,80) = .538$; $p = 0.708$
Between-Subjects Effects	
Sex	- $F(1,80) = .087$; $p = 0.769$
Age	- $F(1,80) = 11.266$; $p = 0.001$
Interaction between Age X Sex	- $F(4,80) = 1.308$; $p = 0.256$

The results show a significant main effect for age and a significant interaction between age and BSI dimensions. The BSI dimensions do not demonstrate a significant main effect although the F value was approaching statistical significance. Sex does not have a main effect or have any interaction effects.

It seemed likely from viewing Figure 9 above that in the over 60 age group differences according to sex may exist. Therefore, a two-factor mixed factorial anova was computed for this age group ($N = 60$).

Two-factor mixed ANOVA	
Within-Subjects Effects	
BSI dimensions	- $F(4,66) = 10.099$; $p < 0.001$
Interaction between BSI dimensions X Sex	- $F(4,80) = .165$; $p = 0.956$
Between-Subjects Effects	
Sex	- $F(1,66) = 2.856$; $p = 0.096$

In summary, the anova results reveal a significant relationship between age and level of psychopathology. Younger adults exhibit higher levels of psychopathology than older adults, but greater variation between individual psychopathologies exists within the older adult sample. The effect of sex on level of psychopathology is greater in the older adult group, but not statistically significant. (See Appendix 6(b) for SPSS output.)

Testing the hypotheses

Hypothesis 1(a)

In order to demonstrate significant levels of psychopathology in long-term benzodiazepine users, BSI dimension scores were compared with BSI population norms using a Wilcoxon paired samples test.

Table 12 shows the mean scores for each BSI dimension and the normative cut-off as determined by age and sex. With the exception of anxiety in older females and anxiety and interpersonal sensitivity in older males, all BSI mean dimension scores in the current sample were found to be higher than the corresponding normative cut-off score.

Table 12: Mean scores for each BSI dimension and norm cut-off scores according to age and sex

BSI dimension		Older Females (N = 48)	Older males (N = 20)	Younger females (N = 9)	Younger males (N = 7)
Anxiety	Mean	.47 (SD .63)	.29 (SD .46)	.99 (SD 1.13)	1.23 (SD .55)
	Norm cut-off	.48	.30	.37	.22
Interpersonal sensitivity	Mean	.49 (SD .50)	.28 (SD .38)	.94 (SD .89)	.82 (SD .59)
	Norm cut-off	.40	.32	.35	.25
Somatisation	Mean	.73 (SD .45)	.53 (SD .41)	.82 (SD .86)	.95 (SD .59)
	Norm cut-off	.50	.45	.43	.29
Depression	Mean	.68 (SD .88)	.55 (SD .68)	.72 (SD .76)	.80 (SD .54)
	Norm cut-off	.53	.43	.46	.28
Phobic anxiety	Mean	.38 (SD .32)	.23 (SD .46)	.95 (SD .79)	.94 (SD 1.21)
	Norm cut-off	.25	.17	.19	.08

The Wilcoxon test was used to compare each participants BSI dimension score with its corresponding normative score (determined by age and sex as shown in Table 12). A Wilcoxon test was used because the distribution of the normative scores was too negatively skewed (because of the high proportion of older females who had the same normative score). Table 13 below shows the z-value and significance for each BSI dimension ($N = 84$).

Table 13: Results of the Wilcoxon paired samples test

Test Statistics ^b					
	Anxiety mean- Anxiety norm	Interpersonal mean- Interpersonal norm	Somatisation mean- Somatisation norm	Depression mean- Depression norm	Phobic mean- Phobic norm
Z	-.458 ^a	-1.309 ^a	-3.620 ^a	-.714 ^a	-1.777 ^a
Asymp. Sig. (1-tailed)	.323	.095	.000	.237	.037

a. Based on negative ranks.
b. Wilcoxon Signed Ranks Test

Out of the five BSI dimensions, somatisation and phobic anxiety demonstrated significantly higher levels than normal levels of somatisation and phobic anxiety in the general population.

Rejection of the null hypotheses: The results found that those individuals in receipt of a long-term repeat prescription for benzodiazepines demonstrated statistically significant levels (in descending order of significance) of somatisation and phobic anxiety ($p < .05$). Hypothesis 1(a) is therefore upheld.

Hypothesis 1(b)

In order to test the hypothesis that psychopathology will predict benzodiazepine dependence a regression analysis was computed.

There were two options for regression analysis. The first was to select multiple regression analysis, using total SDS score as the dependent variable and BSI dimensions as the independent variables. This option examined whether psychopathology (i.e. scores across the five BSI dimensions) predicts scores on the SDS.

The second option involved the use of logistic regression analysis in order to examine whether psychopathology predicts benzodiazepine dependence. In this example the dependent variable is a dichotomous one (dependence/no dependence). The author felt that to predict category membership would be a more useful procedure. However, the results of a logistic regression analysis using the current data set would need to be interpreted with caution, because as previously discussed the reliability of the SDS as a measure of benzodiazepine dependence with the current subject sample was questionable. The finding that the original cut off score for benzodiazepine dependence did not detect dependence in the current cohort prompted the cut off score to be reduced to 4. For this reason a multiple regression analysis was computed first to establish whether psychopathology could significantly predict SDS scores. Had this analysis not been statistically significant it could have been considered somewhat questionable to analyse the data further using logistic regression to predict category membership.

Multiple regression

Multiple regression casewise diagnostics found no outliers. A scatter plot found no discernible pattern, confirming that the assumptions of linearity and homogeneity of variance had been met.

Table 14 reports the results of a stepwise regression analysis. Only two BSI dimensions achieved the entry criterion: anxiety and somatisation. The best model fit would appear to be model 2, which includes anxiety and somatisation as both of these coefficients are statistically significant. Model 2 accounts for 20.1 per cent of the variance in the dependent variable ($F(1,82) = 11.432; p < 0.001$).

Table 14: Results of the Multiple Regression Analysis for dependent variable SDS score

Model Summary					
Model		R	R Square	Adjusted R Square	Std. Error of the Estimate
1		.417 ^a	.174	.164	2.1507
2		.469 ^b	.220	.201	2.1025

a. Predictors: (Constant), LNaNX

b. Predictors: (Constant), LNaNX, LNSOM

ANOVA^c						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	79.868	1	79.868	17.268	.000^a
	Residual	379.275	82	4.625		
	Total	459.143	83			
2	Regression	101.070	2	50.535	11.432	.000^b
	Residual	358.073	81	4.421		
	Total	459.143	83			

a. Predictors: (Constant), LNaNX

b. Predictors: (Constant), LNaNX, LNSOM

c. Dependent Variable: total SDS

Coefficients^a						
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	3.159	.359		8.812	.000
	LNaNX	1.073	.258	.417	4.155	.000
2	(Constant)	1.989	.639		3.112	.003
	LNaNX	.766	.289	.298	2.650	.010
	LNSOM	.919	.420	.246	2.190	.031

a. Dependent Variable: total SDS

Logistic regression

The result of the logistic regression analysis found that the BSI dimensions together explain 43 per cent of the variance in the dependent variable (benzodiazepine dependence using a SDS cut off of 4). This result is statistically significant as illustrated by the Chi-square value. However, the use of the backward stepwise option in logistic regression allowed for closer examination of the relative importance of each of the BSI dimensions. This consideration was relevant in order that the “best model” to explain the variance found in the dependent variable could be posited.

See Appendix 6(c) for SPSS print out for all regression analyses

Table 15: Results of the Logistic Regression Analysis for dependent variable BZD dependence

Omnibus Tests of Model Coefficients				
		Chi-square	df	Sig.
Step 1	Step	32.350	5	.000
	Block	32.350	5	.000
	Model	32.350	5	.000
Step 2 ^a	Step	-.004	1	.951
	Block	32.346	4	.000
	Model	32.346	4	.000
Step 3 ^a	Step	-2.557	1	.110
	Block	29.789	3	.000
	Model	29.789	3	.000
Step 4 ^a	Step	-2.450	1	.118
	Block	27.339	2	.000
	Model	27.339	2	.000

a. A negative Chi-squares value indicates that the Chi-squares value has decreased from the previous step.

Model Summary			
Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	77.146	.320	.439
2	77.149	.320	.439
3	79.706	.299	.410
4	82.156	.278	.381

Model if Term Removed ^a					
Variable		Model Log Likelihood	Change in -2 Log Likelihood	df	Sig. of the Change
Step 1	ANXMEAN	-43.278	9.411	1	.002
	INTMEAN	-39.804	2.463	1	.117
	SOMEAM	-40.156	3.167	1	.075
	DEPMEAN	-41.195	5.244	1	.022
	PHOBMEAN	-38.575	.004	1	.951
Step 2	ANXMEAN	-43.318	9.488	1	.002
	INTMEAN	-39.879	2.609	1	.106
	SOMEAM	-40.184	3.219	1	.073
	DEPMEAN	-41.259	5.368	1	.021
Step 3	ANXMEAN	-43.544	7.382	1	.007
	SOMEAM	-41.082	2.459	1	.117
	DEPMEAN	-41.517	3.327	1	.068
Step 4	ANXMEAN	-46.425	10.695	1	.001
	DEPMEAN	-43.093	4.030	1	.045

a. Based on conditional parameter estimates

Table 15 shows that anxiety and depression offer the best model for predicting the dependent variable (38.1 per cent of the variance). Inclusion any of the others BSI dimensions, or any first order interaction, does not significantly increase variance accounted for. Examination of

the “change in -2 Log likelihood” statistic in Table 15 found that anxiety makes the strongest contribution to the model, as to remove anxiety as a predictor increases the -2 Log likelihood statistic significantly more than the removal of any other predictors. (See Appendix 6(c) for the SPSS printout)

Rejection of the null hypotheses: Anxiety and depression were found to explain a significant proportion of the variance in the dependent variable (38 per cent). On the basis of these results it is posited that anxiety and depression are significant predictors of benzodiazepine dependence. Therefore Hypothesis 1(b) which states that psychopathology will predict benzodiazepine dependence is upheld.

Hypothesis 2

Hypothesis 2 predicted that long-term users of benzodiazepine medication would show evidence of poorer sleep quality, as measured by the Pittsburgh Sleep Quality Index. This hypothesis was tested using a one sample t-test. The authors of the PSQI (Buysse et al 1989) published mean global and component scores, across four diagnostic groups including controls. Controls were described as “healthy control subjects without sleep complaints” (p.195).

The mean global PSQI score for healthy controls was reported as 2.67, this figure was selected as the test value for a one sample t-test ($N = 84$).

One-Sample Test						
	Test Value = 2.67					
	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
global score	18.970	83	.000	8.4014	7.5205	9.2823

The results of the one sample t-test demonstrate a very significant difference between the mean global PSQI score found in the current sample and the mean global PSQI score for healthy controls.

Rejection of the null hypotheses: The results found that long-term users of benzodiazepine medication demonstrated significantly poorer sleep quality than healthy controls therefore Hypothesis 2 is upheld.

Hypothesis 3

Hypothesis 3 predicted that those individuals exhibiting poorer sleep quality would have increased levels of psychopathology.

Table 16 below shows that each BSI dimension correlates significantly with global PSQI score demonstrating that increased levels of psychopathology is associated with poorer sleep quality.

Table 16: Correlation coefficients to show the relationship between psychopathology and global PSQI score

Correlations		
		global score
global score	Pearson Correlation	1.000
	Sig. (2-tailed)	.
	N	84
total raw bsi	Pearson Correlation	.515**
	Sig. (2-tailed)	.000
	N	84
ANXIETY	Pearson Correlation	.502**
	Sig. (2-tailed)	.000
	N	84
INTERPERSONAL	Pearson Correlation	.232*
	Sig. (2-tailed)	.033
	N	84
SOMATISATION	Pearson Correlation	.443**
	Sig. (2-tailed)	.000
	N	84
DEPRESSION	Pearson Correlation	.408**
	Sig. (2-tailed)	.000
	N	84
PHOBIC ANXIETY	Pearson Correlation	.334*
	Sig. (2-tailed)	.002
	N	84

** = p< 0.01 level
 * = p< 0.05 level

A multiple regression analysis was computed to explore which of the BSI dimensions best predict poorer sleep. Table 17 reports the results of a stepwise regression analysis. Only two BSI dimensions achieved the entry criterion: anxiety and somatisation. The best model fit would appear to be model 2, which includes anxiety and somatisation as both of these coefficients are statistically significant. Model 2 accounts for 28.7 per cent of the variance in the dependent variable ($F(1,82) = 17.718; p = <0.001$).

Table 17: Results of the Multiple Regression Analysis for dependent variable PSQI global score

Model Summary^c

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.502 ^a	.252	.243	3.5312
2	.552 ^b	.304	.287	3.4271

a. Predictors: (Constant), LNaNX

b. Predictors: (Constant), LNaNX, LNSOM

c. Dependent Variable: global score

ANOVA^c

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	345.102	1	345.102	27.676	.000 ^a
	Residual	1022.470	82	12.469		
	Total	1367.571	83			
2	Regression	416.203	2	208.102	17.718	.000 ^b
	Residual	951.368	81	11.745		
	Total	1367.571	83			

a. Predictors: (Constant), LNaNX

b. Predictors: (Constant), LNaNX, LNSOM

c. Dependent Variable: global score

Coefficients^a

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	8.730	.589		14.830	.000
	LNaNX	2.231	.424	.502	5.261	.000
2	(Constant)	6.587	1.042		6.323	.000
	LNaNX	1.668	.471	.376	3.542	.001
	LNSOM	1.683	.684	.261	2.460	.016

a. Dependent Variable: global score

Rejection of the null hypotheses: The results found (in descending order of significance) that anxiety, somatisation, depression, phobic anxiety and inter-personal sensitivity are significantly correlated with poorer sleep. Anxiety and somatisation were found to significantly predict poorer sleep. Hypothesis 3 was therefore upheld.

Hypothesis 4

Hypothesis 4 predicted that individuals exhibiting greater dependence would be less psychologically minded. Table 18 below shows that the difference between mean PMS scores for dependent and non dependent groups is not statistically significant. Therefore the null hypothesis can not be rejected.

However, a statistically significant difference in PMS score was found between those individuals who used their benzodiazepines every day and those individuals who chose not to take them every day.

Table 18: Mean PMS scores according to BZD dependence and frequency of BZD use

		Mean PMS score	SD	t-value	df	One-tail sig
Benzodiazepine Dependence	Dependent	119.66	12.27	1.606	82	0.056
	Not dependent	124.50	14.77			
Frequency of Benzodiazepine use	Daily	119.18	11.60	2.556	82	0.006
	Not daily	127.26	15.96			

SUMMARY OF HYPOTHESIS TESTING

- The results found that those individuals in receipt of a long-term repeat prescription for benzodiazepines demonstrated significantly higher levels of somatisation and phobic anxiety than the normal population. Hypothesis 1(a) was therefore upheld.
- The results found that anxiety and depression were found to be significant predictors of benzodiazepine dependence. Hypothesis 1(b) was therefore upheld.
- The results found that the long-term use of benzodiazepine medication does not relieve insomnia. Hypothesis 2 was therefore upheld.
- The results found that anxiety, somatisation, depression, phobic anxiety and inter-personal sensitivity are significantly correlated with poorer sleep; with higher levels of

psychopathology found to accompany poorer sleep. Anxiety and somatisation were found to significantly predict poorer sleep. Hypothesis 3 was therefore upheld.

SUMMARY OF ADDITIONAL SIGNIFICANT RESULTS

- Significant differences were found in the mean number of years in receipt of benzodiazepines according to type.
- Living alone and benzodiazepine use only demonstrates a significant relationship when benzodiazepines are commenced following bereavement.
- Pain was found to be significantly associated with poorer sleep, higher dose of benzodiazepine and increased frequency of benzodiazepine use.
- Participants who use benzodiazepines less frequently are significantly more likely to consider stopping them.
- Males are significantly more likely than females to consider stopping benzodiazepines.
- Older benzodiazepine users are significantly less psychologically minded than younger benzodiazepine users.
- Younger benzodiazepine users exhibit significantly more psychopathology than older benzodiazepine users. More variation across different types of psychopathology was found in older benzodiazepine users.
- Daily benzodiazepine users were found to be significantly less psychologically minded than infrequent benzodiazepine users.

Chapter 9: Discussion

This final chapter discusses the results of the study and examines their significance and clinical implications. Limitations of the research study are considered.

Relating the findings of the current study to the published research on long-term benzodiazepine use

Prevalence rates of benzodiazepine use vary considerably. Chapter 1 reported that general prevalence rates range from 2.2 per cent to 17.6 per cent. However, focusing more closely on long-term use in primary care samples, the literature highlights a much higher proportion of older adults in receipt of long-term benzodiazepines, with the rate of benzodiazepine users per 1000 rising steadily across age bands (Chapter 5). Published prevalence rates in older adults were rarely found to be less than 10 per cent. The literature also indicates that whilst the prescribing of anxiolytics has reduced, the use of hypnotics with older persons has remained fairly constant (Taylor et al 1998). In the present study, a small percentage of long-term benzodiazepine users were in receipt of anxiolytics for anxiety disorders, although diazepam which is an anxiolytic, was being used for sleep and associated medical health problems. Whilst the general prevalence rate in the practice population studied was relatively low (2.8 per cent) compared with other published studies, when this figure was examined more closely prevalence rates in older adults were found to be considerably higher, especially older females. Therefore, the study reflects the current prescribing trend with respect to benzodiazepine use (i.e. higher levels of prescribed hypnotics with older adults).

It is clear from the data presented in the Results section that recommended prescribing guidelines for benzodiazepines have not been adhered to with regard to participants in the

current study. Almost 20 per cent of the sample was taking more than the BNF recommended dose. More worrying was the finding that participants had been taking their benzodiazepines for an average of 10 years; this figure far exceeds the recommendation of 4 weeks. In addition, over half the sample was prescribed a longer-acting benzodiazepine, which, as discussed in the introductory chapters, is more likely to give rise to adverse effects over time, particularly with older patients for whom the specific risk factors have been well publicised. The literature proposes that the long-term use of hypnotics is likely to produce tolerance. Whilst one can only speculate as to the presence of tolerance in the current sample, it would not be unreasonable to suggest that a significant proportion of the sample will have developed tolerance to their benzodiazepine medication, in view of the length of time that they have been using it. It is therefore probable that these participants will no longer gain any physiological benefit from using benzodiazepines. This is one possible explanation for the significantly high PSQI scores, which demonstrate that despite the use of “sleeping pills” 90 per cent of the sample report insomnia. This finding is in line with the Committee on the Review of Medicines (1980) and the White House Office of Drug Policy and National Institute on Drug Abuse (1979), who reported on the loss of efficacy of hypnotics with continuous use. What is troubling about the finding that long-term hypnotic use is ineffective in treating insomnia, is the fact that this information was reported over 20 years ago, yet the current study demonstrates that individuals are still being *commenced* on long-term repeat prescriptions for hypnotics.

The age distribution of the sample showed that the largest group (35 per cent) in receipt of benzodiazepines was over 80 years old. This finding is in line with prevalence rates reported in Chapter 5 by Simpson et al (1990). The general perception of long-term benzodiazepine use in older samples is that the most elderly persons are likely to have been taking their benzodiazepines for the longest period of time. In the current sample no association was found between age and the length of time a patient had been prescribed benzodiazepines. In

addition, of those patients commenced benzodiazepines in the past 5 years nearly 50 per cent were over the age of 70 years. Therefore, despite the evidence that older persons are most at risk of adverse effects from benzodiazepine use, it would appear that they are still the most likely group to be commenced on long-term repeat prescriptions.

The PSQI identified 90 per cent of the sample to be poor sleepers. Sleep efficacy was found to be the most problematic of the seven sleep components comprising the PSQI. Participants spent a mean of 9 hours in bed per night but slept an average of 6 hours; this amounts to poor sleep efficiency. However, as reported in Chapter 2, ageing affects sleep requirement and by the age of 60 years most individuals will only require around 6 hours sleep. Therefore, the majority of participants were actually meeting their sleep requirement. Changes in sleep duration and sleep architecture are a normal part of the ageing process, which means that an increase in nocturnal awakenings and reduced sleep duration are a normal, not abnormal feature of sleep as one gets older.

It is possible that sleep problems within the sample were, to some extent, related to unrealistic expectations of sleep rather than actual sleep deficiencies. It has been suggested that older adults prefer to spend more time in bed, not because they are tired but because of boredom, social isolation and lack of purposeful activity. Therefore, retiring to bed “early” contributes to poor sleep efficacy, but closer examination of the raw data reveals that for many older participants sleep duration was adequate. This feature of the participants sleep habits is further confirmed by the finding that sleep latency (time taken to fall asleep) was the second most problematic component. Furthermore, the prevalence of daytime dysfunction was relatively low in the sample; of the seven PSQI component scores daytime dysfunction was the lowest. This would suggest that lack of sleep was not considerable enough to impair daytime functioning. Instead, as psychopathology was found to significantly correlate with daytime dysfunction, it was possible that in the current sample psychopathology played a bigger part in daytime dysfunction than did lack of sleep.

In addition, it has been shown that a mismatch exists between subjective and objective measures of sleep duration. Schneider-Helmert (1988) found that patients given benzodiazepines overestimated their sleep duration by an average of 72 minutes as measured by EEG recordings. In the same sample, when benzodiazepines were withdrawn the patients underestimated the duration of their sleep by an average of 1 hour. It is possible that within the current sample many participants “believe” themselves to be poor sleepers and this had been reinforced by their long-term use of benzodiazepines. This belief may have inadvertently influenced their self-report on the sleep measure.

In contrast to previous research evidence, some of the demographic features of insomnia were not replicated in the current study. For example, as cited in the Introduction, insomnia has been reported to be associated with older age, living alone and being female. The study found no difference in PSQI scores across these groups. However, as PSQI scores were high throughout the sample comparative analysis was self-limiting.

Each BSI dimension significantly correlated with total PSQI global score. Somewhat surprisingly (because sleep problems are a diagnostic indicator of depression) although depression correlated with poorer sleep it was not found to be a significant predictor of poor sleep. In the current sample anxiety and somatisation were found to be significant predictors of poorer sleep. Not surprisingly participants who were found to be dependent on benzodiazepines had a significantly higher PSQI score. However there was no significant difference in PQSI score between daily and less frequent benzodiazepine users. This is further evidence that in this sample long-term use of benzodiazepines does not assist sleep.

The results found that participants gave a range of different reasons for commencing benzodiazepines. With the exception of six participants that reported anxiety as the primary reason for their benzodiazepine use, the sample reported that sleep difficulties had prompted their original presentation to their general practitioner. However 38 per cent of this group were unable to identify a reason or precipitant for their sleep problems. Very few participants

seemed concerned about the length of time they had been taking their benzodiazepines and belief in the efficacy of their benzodiazepines was very strong. Participants for whom the original reason for commencement on benzodiazepines was no longer pertinent seemed to be unconcerned that years later they were still taking them. Typical responses to the question of “What is the current reason for your use of benzodiazepine medication?” were: (i) “I’ve always been a bad sleeper”; (ii) “I would get even less sleep than I do already if I didn’t take a sleeping pill”; (iii) “I’m a light sleeper, the pills give me a better sleep”. Most participants said that without benzodiazepines their amount of sleep would be considerably less than it currently was, and some participants reported that they were convinced that they would not sleep at all.

Bereavement, stress or worry and pain were the three most common reasons for commencing repeat prescription benzodiazepines. The “medical” reasons for commencement of benzodiazepines, for example, pain, muscle spasms and tinnitus remained constant over time. Psychological reasons for commencing benzodiazepines, for example, worries, depression and bereavement, were found to disappear over time. Nevertheless, these participants continued to use their benzodiazepines, as they believed they would not be able to sleep without them.

Although research has shown that older persons who live alone to be more likely to use long-term benzodiazepines (Pinsker and Suljaga-Petchel 1984). No relationship was found between the length of time in receipt of benzodiazepines and the length of time that an individual had lived alone, unless benzodiazepines were commenced following bereavement. Similarly, there was no difference in the reasons given for commencing benzodiazepines according to whether a patient lived alone or with a partner, when bereavement was excluded from the analysis.

Fifteen per cent of the sample were commenced on benzodiazepines following the loss of their spouse; for most of these participants their bereavement was over 10 years previously.

The usual features of bereavement normally include crying and sadness, anxiety, insomnia and loss of appetite (Institute of Medicine 1998). However, using benzodiazepines, which may provide relief in the short term with such symptoms, is not helpful long term. Bereavement is a risk factor for depression (and therefore suicide), with between 10 and 20 per cent of widowed people developing clinically significant symptoms of depression within the first year following bereavement (Report of the Surgeon General 1999). The institution of benzodiazepines may mask a diagnosis of either adjustment disorder or depression with the result that an individual would not receive appropriate treatment.

One of the surprising findings of the study was the lack of impact that medical conditions appeared to have on the participants sleep and psychopathology. Chapter 2 presented evidence that insomnia is frequently linked to a number of medical conditions and/or the drugs used to treat such conditions (Kales and Kales 1984). Zancocchi et al (1999) found that in an elderly sample, number of medications significantly correlated with poor sleep as measured by the PSQI. However, whilst the participants in the current study experienced most of the medical conditions and used the medications reported by Kales and Kales, no statistical association was found between the number of health conditions and poorer sleep. Nevertheless, it was not possible to compare poor sleepers/good sleepers with medical problems/no medical problems because almost the whole sample were poor sleepers with medical conditions, therefore the effect on sleep of medical conditions may well have existed in the sample but was not measurable. As one might predict a small but statistically significant relationship was found between increased health problems and higher somatisation scores. In addition, participants experiencing more health problems were also found to take higher doses of benzodiazepines.

The study did find a significant relationship between pain, poorer sleep and increased use of benzodiazepines. The two medical categories that were significantly associated with the use

of pain relief were musculoskeletal conditions and gastro-intestinal conditions; most commonly reported painful conditions included rheumatoid arthritis, osteoarthritis, ulcers of the digestive tract or stomach cramps. This finding is in line with the Kupperman et al (1995) research, cited in Chapter 2, which proposed that it is the painful feature of many medical conditions that contributes most to sleep problems.

A large proportion of the sample did not wish to stop using benzodiazepines; females were significantly less likely to want to stop than males. In addition, participants that used benzodiazepines less frequently were significantly more likely, than daily users, to want to stop taking them. The average participant that did not wish to stop taking their benzodiazepine medication was older, took a higher dose and had been taking them for longer, than the average participant who wanted to stop taking them.

As reviewed in Chapter Five older adults have been found to be much less likely to want to stop benzodiazepine medication (Wright et al 1994). In view of the mean age of the current sample (72), it is not surprising that this finding was replicated. One possible explanation for the lack of interest within the sample to stop their benzodiazepine medication may lie with the concept of psychological mindedness.

Psychological mindedness and psychological treatments with older people

Although, scores on the PMS were well below the population average (mean percentile rank of 28), participants who reported that they used their benzodiazepines less frequently were found to have significantly higher scores on the psychological mindedness scale.

Analysis found a significant association between age and PMS scores, with older adults found to be less psychologically minded. The authors of the PMS described individuals low on psychological mindedness as representing “a group one would not expect to be insightful nor be open to, motivated for, or have the capacity for change” (p.18) What the present study

cannot tell us (because it did not include a control group) is whether being less psychologically minded is a feature of older long-term benzodiazepine users or a general feature of older age. Nevertheless, this is a significant finding as it suggests that psychological mindedness could be a key determinant in the willingness to stop benzodiazepine medication. It is therefore an area that warrants consideration in the search to find ways to encourage long-term benzodiazepine users to stop their benzodiazepine medication.

Of the three psychological mindedness scales reviewed for the current study it would appear that none has been tested specifically on an older population. The normative data for psychological mindedness scales derives from students and young adult samples and is a limitation of using the PMS with older adults. Normative data for this age group would allow a more accurate assessment of psychological mindedness in older adults.

Another problem with the PMS was the length of the questionnaire. For individuals not used to filling in questionnaires, or individuals with less education and literacy skills, the 45 “difficult” items were found to be tedious and time consuming. Participants commented that they found the PMS items “hard to understand” and that they were repetitive. In addition, eight of the PMS items asked the respondent about trying out new behaviours, one such example “I like to try new things even if it involves taking risks”. The more elderly members of the sample remarked that due to frailty or current health problems, trying new things and taking “risks” was not an option for them. More meaningful responses might have been elicited from respondents if the items had not been worded in the present tense, but in such a way that did not allow current health and other difficulties to restrict the way an older person could respond.

The issue of psychological mindedness bears some relation to a much-debated topic in the older-adult research literature regarding the efficacy of psychological therapies with older adults. Older adults are often overlooked in terms of access to psychological treatments and a

number of reasons for this situation have been proposed. Many older adults present with sub-clinical conditions, or with atypical symptomatology that makes assessment and diagnosis of mental health problems more difficult. In addition, diagnosis of mental health problems in older adults is often further complicated by high comorbidity with other medical disorders (Report of the Surgeon General 1999). There are also stereotypes about normal ageing, for example the “understandability phenomenon” (Blanchard 1996), which suggests that depression and hopelessness are to be expected in older age as a consequence of losses or bereavement and the common misconception that an older person is not capable of change (Stanley and Averill 1999). These factors can serve as a barrier to psychological treatment with the result that older adults are not referred for psychological therapies. This situation creates a “vicious circle” whereby older people do not get the opportunity to learn about and benefit from psychological input. This maintains the belief that psychological approaches are less appropriate for the older person, which denies the older person the opportunity to develop more psychological ways of thinking.

This is not to say that sometimes a different approach might need to be adopted when working psychologically with older adults. However, this is usually little more than careful socialisation to psychological ways of approaching emotional problems and dispelling the misconceptions or cohort beliefs an older person may have about therapy.

If an older person has had a limited experience of psychological ways of thinking about and approaching problems, this would explain poorer scores on a measure such as the PMS. For example a common theme in the PMS is the notion that talking about worries and problems can be helpful. However, if an individual has never been encouraged, or had the opportunity to do this, they would be less likely to view talking about problems as potentially beneficial.

Measuring benzodiazepine dependence in primary care

An important feature of the current study, which proved to be difficult to evaluate, was the issue of benzodiazepine dependency. The prevalence of benzodiazepine dependency, whether dependency was physiological or psychological and how best to measure it, all proved to be difficult factors to assess.

The SDS was originally developed as a short self-report scale for measuring drug dependency across a range of drugs. Adapted by De la Cuevas et al (2000) for use with benzodiazepine users, the authors claimed that its items were “explicitly concerned with psychological components of dependence” (p.246).

The pilot study (see Appendix 1) established that the sample population was reluctant to consider that they could be “dependent” on benzodiazepines. The use of the word “addicted” was forcefully denied by all the participants in the pilot study. Therefore, a questionnaire that did not use such terminology was considered to be most appropriate. In addition, it appeared that those individuals who took their benzodiazepines every day rarely missed a dose. This gave rise to a situation in which symptoms of withdrawal, recurrence or rebound had not been experienced to any significant degree. In addition, over 60 per cent of the sample were prescribed a benzodiazepine with a long half-life. This meant that should a single dose be missed, owing to the cumulative effects of the longer-acting benzodiazepines, withdrawal symptoms are not immediately in evidence. Therefore, to have asked participants about withdrawal symptomatology would not have been very productive because, for this sample, withdrawal was not a salient issue.

That is not to say that participants would not experience withdrawal if they suddenly stopped their benzodiazepines. Chapter 1 reviewed the prevalence of withdrawal reactions following discontinuation of benzodiazepines. It is highly likely that owing to their long-term usage, a large proportion of the sample would experience some degree of withdrawal if they stopped their benzodiazepines, particularly in the absence of a gradual taper regime.

In view of participants' limited experience of withdrawal (which is frequently used as a measure of physiological dependence), the selection of a questionnaire that measured psychological dependency had seemed most appropriate. However, the psychological components of the SDS items focus on "impaired control over drug taking" and "anxieties about drug use". It was found that these aspects of benzodiazepine use were not considered to be a problem by the participants in the current sample and consequently only a small amount of dependency was detected in the sample when the SDS was used with the suggested cut off score of seven.

It is proposed that this finding is best explained by consideration of the context in which long-term benzodiazepine use occurs for this cohort of users. Long-term repeat prescribing of benzodiazepines is most commonly seen in primary care settings. In this context a patient usually has a well-established and trusted relationship with their general practitioner. In addition, older patients are reported to be more compliant about taking psychoactive medications than other types of medication (Cooper et al 1982). Under these circumstances it is unlikely that patients would question the appropriateness of their benzodiazepine medication, especially if they take other medications for more serious medical conditions. In such cases it is probable that the importance of compliance and adherence has been impressed upon them. For many older persons, taking medications every day is a well-established and unquestioned behaviour.

When participants were asked if they had ever questioned the use of their benzodiazepines, they responded with comments such as "My doctor wouldn't give me them if they weren't safe" or "I've been taking them for years and they've not done me any harm".

The procedure of repeat prescribing, which does not involve frequent patient doctor consultation, could give the patient the impression that there is very little to be concerned about with regard to the use of benzodiazepines. This attitude was reflected in the responses to the question in the SDS that asked if the respondent had any worries about using benzodiazepines ("Did you worry about the use of your tranquillisers?"). Similarly, when

asked if they thought their benzodiazepine use was out of control (“Did you think your use of tranquillisers was out of control?”) participants overwhelmingly said that it was not, because they took their tablets as prescribed. The two SDS items that appeared to measure benzodiazepine dependence more reliably were “perceived difficulty to stop benzodiazepines” and “concern about missing a dose”. Although these concerns were because the participants were worried about not sleeping, not about withdrawal.

The SDS therefore proved to be less than satisfactory in identifying dependence in the current cohort. Despite having face validity in practice the SDS items demonstrated poor internal consistency, as they did not correlate well with each other (range 0.04–0.44). The Results section presented evidence to support a reduced cut-off SDS score in the current sample in order to increase the sensitivity of the measure. Ideally, to select an appropriate cut off score on the SDS for this sample, the study should have included another standardised measure of dependency with normative data for older adults, against which to assess the SDS. Instead *frequency of benzodiazepine use* was selected as a “rough guide” to gauge the presence or absence of dependency. It was not the intention to suggest that the frequency of use variable was “better” than the SDS in detecting benzodiazepine dependence, rather that it was useful in highlighting the rationale underpinning the decision to reduce the SDS cut-off.

Poor reliability demonstrated by both the PMS and SDS with this sample could be partly attributable to the cohort beliefs found within the sample. Thus highlighting the problem of using measures that have been developed with other types of client group. The (older) primary care sample in the current study held beliefs that were incongruent with the themes being measured by the SDS questionnaire. In particular, the notion of dependency was not regarded as relevant by the participants, who appeared to hold stereotypical views about “drug addicts” as very distinct from themselves. Alternatively, if the PMS did reliably measure psychological mindedness, thus demonstrating that older people are less

psychologically minded, this could explain why the SDS (designed to measure the psychological component of dependency) was not a useful measure with the current sample. The problems observed with the use of the SDS in the current setting emphasise the need for a dependency measure specifically designed for older people. In addition, the PMS could be made more applicable for older adults by rewording items to account for limitations that accompany normal ageing, as these may have affected the ways in which respondents answered the questions.

Psychopathology in long-term benzodiazepine users

The BSI was used to measure anxiety, depression, somatisation, phobic anxiety and interpersonal sensitivity. Psychopathology was examined in relation to insomnia and benzodiazepine dependency. Elevated levels of psychopathology were found across the total sample, with the prevalence of somatisation found to be greater than the other psychopathologies. This was not a surprising finding as the literature suggests that older adults are more likely to report somatic symptoms (Blazer 1996) and that somatisation has been found in up to 37 per cent of patients with severe insomnia (Mellinger et al 1985). Chapter 3 reported that generalised anxiety was more prevalent than other anxiety disorders, however, the combined prevalence of phobic disorders (agoraphobia, simple phobia and social phobia) in older adults has a reported prevalence rate of 10 per cent (Lindesay et al 1989). This may explain the higher scores for phobic anxiety rather than anxiety, as measured by the BSI in the current sample. Although older women were found to exhibit higher levels of symptomatology than did older men, this difference was not significant. Previous research has found that, in general, women are more likely to experience higher levels of psychopathology than men. However, this finding is less consistent in older adult samples, with a number of published studies presenting conflicting results (Hale and Cochran 1983). In the current study, as psychopathology appears to be associated with

benzodiazepine use, this is likely to offset potential sex differences and, indeed, no significant sex differences were found.

While both somatisation and anxiety were found to significantly predict sleep difficulties, anxiety was shown to be a much stronger predictor. A similar result was found for severity of dependence in that somatisation and anxiety were found to be significant predictors, but again anxiety demonstrated a larger effect. When dependence was measured as category membership, anxiety and depression were significant predictors, but yet again anxiety was the main predictor. Because sleep difficulties and benzodiazepine use are associated in this study, it is not possible to determine whether the relationship between anxiety and sleep, and anxiety and dependency, are independent of one another, or whether they are the same relationship. To tease out the relationship between dependency, sleep and anxiety would have required a further comparison including participants that used benzodiazepines but did not still have a sleep problem.

The key finding, therefore, is that of the psychopathologies investigated, the prevalence of somatisation was greater than other psychopathology, but that anxiety was the most significant feature of sleep difficulties and long-term benzodiazepine dependence, although it is not possible to establish the causal factors in this association.

Some studies have shown that significant levels of anxiety and depressive symptomatology are to be found in those individuals that have been using benzodiazepines long term. When such individuals were successfully withdrawn from their benzodiazepines, many were shown to have significantly improved anxiety and depression scores. The conclusion from this finding was that long-term benzodiazepine use might worsen anxiety and depression (Schweizer et al 1990). Therefore, whilst the institution of benzodiazepines is likely to provide some relief in the short term, in the long term the patient is not helped by their continued use and may even feel worse. This could be due to either physiological effect such as tolerance and rebound effects and or the psychological effects of psychological dependence.

Psychological treatment approaches for anxiety and insomnia in older adults

The results of the present study suggest that it may make more sense for insomnia to be viewed as an anxiety problem. The treatment of anxiety has moved on since the 1960s and 1970s when Valium was readily prescribed, and this is reflected in the drop in anxiolytic prescriptions. The preferred choice for the treatment of anxiety is now a psychological approach (Nathan and Gorman 1998). What remains unclear is why the treatment of insomnia has not seen a similar shift in approach from the use of pharmacological to psychological intervention. Could this be because the treatment of insomnia mainly concerns older adults who, as mentioned previously, are less likely to be referred for psychological therapies?

Psychotherapeutic interventions for anxiety disorders in older adults have not been as well-researched as in younger populations, for whom a well-established body of evidence has found psychological interventions to be efficacious (Sunderland et al 1991). In contrast, the study of depression in older adults has received more attention with regard to the efficacy of psychological treatment, with a number of meta-analyses reporting significant results in favour of psychological treatments for late-life depression, particularly the use of cognitive behaviour therapy (Laidlaw 2002). Nevertheless, non-pharmacological anxiety treatments for older adults have shown that the use of psychological interventions can be effective, for example the use of relaxation techniques (DeBerry et al 1989; Scogin et al 1992) and cognitive behaviour therapy (King and Barrowclough 1991; Stanley et al 1996; Gorenstein et al 2000). With growing evidence to support the use of cognitive behaviour therapy (CBT) for late life depression there does not appear to be any reason why the use of CBT for anxiety in older adults could not prove to be equally effective.

Approaches to the psychological treatment of insomnia with older adults include anxiety management techniques such as relaxation training (Bootzin and Perlis 1992) and the use of

CBT to target maladaptive cognitions (Morin et al 1995). Other efficacious behavioural approaches used to treat insomnia include stimulus control therapy, sleep restriction therapy and sleep hygiene education (Nowell et al 1998).

“No systematic data support the idea that elderly patients are too old for psychological change. Most experts agree that, provided cognitive function is intact, elderly patients respond well to psychotherapeutic interventions.” (p.45 Small 1997).

Therefore, if effective psychological treatments for anxiety and insomnia are available, why then within the older adult population are they not more widely employed. This brings the discussion back to the issues raised earlier regarding the use of psychological therapies with older people.

In terms of approaches to benzodiazepine withdrawal, psychological input such anxiety management and support with gradual-taper regimes have also been found to be beneficial. Jones (1991) reported a randomised controlled trial in a primary care setting ($N = 200$) in which twice as many patients in the treatment group reduced their benzodiazepines compared with control group. Treatment consisted of counselling and relaxation therapy by a practice nurse and a clinical psychologist.

In summary, whether the problems of insomnia are caused by basic misconceptions about sleep requirements in old age, as a result of underlying anxiety owing to psychological distress or health problems or anxieties about discontinuing benzodiazepines, the research evidence shows that psychological approaches offer a safer and more effective treatment option than long-term benzodiazepine use.

The Department of Health made the following statement in a Health of the Nation strategy document “ Further effort is needed to review the use of benzodiazepines and replace them, as necessary, with behavioural, cognitive and psychotherapeutic methods.” (1992).

Methodological issues

Meeting the required sample size was found to be a problem with this study. The projected number of participants required for the study was 91. The study ran into difficulties recruiting this number from the original general practice in which the study was based, which prompted the need to recruit from a second general practice and cost more time. Despite access to a second practice population subject numbers fell short of the estimated requirement (the total number of participants that took part in the study was 84). Fortunately, statistically significant results were achieved despite the shortfall in number.

Although the pilot study had given some indication of the time required for data collection, it proved impossible to predict accurately the amount of time data collection would take. The study was set in a rural setting, with the average home visit involving a return journey of 45 to 50 miles. Therefore visiting the majority of participants in their own homes was very time consuming. One alternative would have been to compose a questionnaire to collect the demographic information, which could have been posted along with the study questionnaire, thus removing the need to visit each participant. Although response rates to postal questionnaires are usually low, because of the time-saving feature of this method more general practices could have been included in the study, which may have resulted in similar total of participants. However, it is questionable whether all participants would have filled in the questionnaire without help, as the PMS questions were reported to be challenging to complete. Also, without the interview the depth of qualitative data would have been absent.

The discussion has already highlighted the problems with the PMS and SDS in an older adult sample. The use of the PSQI was found to identify 90 per cent of the sample as poor sleepers, as this was such a large proportion it raised the question of whether the cut-off of five was set too low for an older sample. A study was located that used a cut-off score of

eight for the PSQI (Fichtenberg et al 2001); however, this was with a sample of brain-injured patients. A further study was found in which the authors of the PSQI examined subjective sleep quality in “healthy” older adults (>80 years). Using the cut-off score of five the results found that “overall sleep quality for the majority (68.1 per cent) of 80-yr-olds fell within a categorically defined range for “good” sleepers” (p.331 Buysse et al 1991). This would suggest that the PSQI cut-off score used was indeed satisfactory.

Participation in the study was voluntary. Forty-eight per cent of the individuals invited to take part chose not to. Unfortunately therefore, the characteristics of these benzodiazepine users remain unknown. A common theme elicited from the individuals that did take part was suspicion about whether they would continue to be prescribed benzodiazepines. This concern was met with reassurance from the researcher in that regardless of the information they gave during their participation in the study, their prescription would not be altered in any way. Most participants appeared genuinely relieved following this reassurance. It is possible that this suspicion prevented a number of potential participants from taking part in the study.

An additional component to the study that had to be omitted due to time constraints was to have included an investigation of the general practitioners views on, and their criteria for prescribing long-term repeat benzodiazepine prescriptions. It would also have been interesting to establish how familiar general practitioners were with the specific problems associated with long-term benzodiazepines in older adults.

A further component to the study originally considered was to utilise the information from the study to inform alternative treatment options. This would have involved helping participants to withdraw from their benzodiazepine medication, using the information gathered from each individual patient to inform their own treatment package. For example, if a participant was found to be experiencing elevated levels of anxiety, an approach

incorporating anxiety management would be more suitable, if on the other hand the sleep problem was due to poor sleep habits, sleep hygiene work may be most appropriate. Unfortunately, very few participants came forward expressing an interest in discontinuing their benzodiazepines.

The main difficulty with the data collected in this study lie with the interpretation of the complex relationships between the principle variables measured. It was not possible to control for the interactions between benzodiazepine dependency, sleep problems and psychopathology. These interactions between the variables prohibit speculation regarding causal relationships. In addition, two further variables, medical health problems and pain, are likely to have confounded these relationships further.

Future directions

The important question that remains unanswered is why do general practitioners continue to prescribe long-term repeat prescription benzodiazepines when all the evidence clearly contraindicates their long-term usage. One answer could be the lack of alternative treatment options available to general practitioners. Whilst the research points to psychological approaches as being the way forward in the treatment of anxiety and insomnia, inequity of access to clinical psychology services continues to be a problem. Referrals to psychology continue to increase, resulting in longer waiting lists as supply does not match demand. General practitioners are therefore faced with a situation in which they have to prioritise which patients they refer to psychology.

Although non-pharmacological treatments inevitably cost more than the price of benzodiazepine medication, there are more cost-effective ways of helping people to discontinue using their benzodiazepines, which can be achieved without recourse to

expensive one-to-one therapy from a clinical psychologist. Within the multidisciplinary setting, clinical psychologists are being increasingly called upon to supervise and support other professionals, such as practice nurses and assistant psychologists, in carrying out basic anxiety management work, sleep hygiene and psychoeducation, which can be carried out individually or in groups. A study by Holden et al (1996) found that general practitioners want to help their patients withdraw from benzodiazepines, therefore clinical psychologists could work together with general practitioners to support them in this objective.

Is it fair, however, to place all the responsibility for the current situation, in which older adults are continuing to use benzodiazepines, despite their lack of efficacy and potentially harmful effects, solely with general practitioners? Participants in the current study were all given the opportunity to discontinue their benzodiazepines with support from their general practitioner and a clinical psychologist. Each participant was given an information leaflet about their benzodiazepine medication, which highlighted the possibility of adverse effects with long-term use. To date, only 7 per cent of the sample has expressed an interest in stopping their benzodiazepines.

Doctors that prescribe benzodiazepines more frequently to older patients than to younger patients may be accused of ageism. However, the issue of ageism is a broader problem based on societal perceptions of old age, to which older people themselves have been found to contribute. Many older people hold the same negative ageist assumptions as do younger people, typically that they are "too old to change". This was a recurring theme encountered in the current study. Fortunately, society's attitudes to old age are changing as shown by the concept of active ageing (WHO, 2002), which is described as the process of optimising opportunities for older people in order to extend healthy life expectancy, productivity and quality of life in older age. This philosophy is at odds with the long-term use of benzodiazepines in older adults.

Conclusion and clinical implications

To conclude, the study found that despite all the evidence contraindicating the use of long-term benzodiazepines, the practice of long-term prescribing of benzodiazepines is still found to be taking place in primary care. Whilst patients present to their general practitioners complaining of sleep difficulties, for many the underlying problem is one of anxiety. The study shows that neither anxiety or insomnia benefit from long-term use of benzodiazepines and it is postulated that over time the disadvantages of long-term usage outweigh any short term benefit.

In order to avoid commencing their patients on benzodiazepine medication general practitioners require an alternative option. It is suggested that psychological approaches offer the most effective alternative to pharmacology.

Recommendations for a proactive strategy based in the primary care setting should include:

- Improved access to psychological treatment approaches.
- Provision of specialist older adult psychology services.
- Increased use of clinical psychologists in their consultancy role.
- Implementation of a treatment protocol which would include a policy of comprehensive assessment.

This research study has shown that the majority of primary care patients on long-term benzodiazepine prescriptions have significant psychopathology and that they are reluctant to consider discontinuation of their benzodiazepines. Therefore, a more proactive strategy incorporating psychological approaches may provide the only realistic option to address the problem of reducing long-term benzodiazepine use in the future.

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APPENDIX 1: PILOT STUDY

Pilot Study: Contents

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PILOT STUDY

Introduction

A pilot study was carried out in order to gather information, which would inform the design of the larger research study.

The pilot study consisted of collecting qualitative and quantitative data relating to patterns of benzodiazepine use in an identified general practice. This general practice comprised four general practitioners with a total of 4988 registered patients over the age of 16 years.

Method

Data collection was undertaken in two stages. Stage one involved auditing existing patient records, using the Health Centre's computerised system of recording patient information. Stage two involved the researcher collecting information directly from a small number of patients who were identified as being in receipt of a repeat prescription for benzodiazepine medication by their general practitioners.

Stage One

The General Practitioner Administration System for Scotland (GPASS) was established in 1984 using software originally developed by a Glasgow general practitioner. GPASS is a national computerised primary care system and is now used in over 84 per cent ($N = 855$) of general practices in Scotland. It allows access to patients' prescription records, for example, which medication a patient is in receipt of, prescribed dose, and frequency of collection of repeat prescriptions. GPASS data was used to answer the following questions:

1. How many patients within the identified practice had been in receipt of a repeat prescription for more than 3 months?
2. Which of the benzodiazepine drugs were most frequently prescribed by the general practitioners? How many patients were prescribed each of the different benzodiazepines?
3. What is the ratio of male to female patients in receipt of a repeat prescription for benzodiazepine medication?
4. Are different benzodiazepine drugs prescribed according to sex?
5. How many patients and what type of benzodiazepine medication is prescribed according to age group?
6. How many patients are in receipt of a repeat prescription according to individual general practitioner?
7. How long have patients been in receipt of repeat prescription?

Stage Two

Participants

Nine participants took part in stage two of the pilot study. Of the nine participants three were female. The age of participants ranged from 52 to 83 years (mean 73.1 years, SD 9.30).

Length of time in receipt of a repeat prescription for benzodiazepine medication ranged from 1 to 17 years (mean 9.44, SD 5.10).

Materials

A semi-structured interview was conducted with each participant and each participant filled in the Hospital Anxiety and Depression Scale (HADS) (Snaith & Zigmond 1994). The HADS is a 14-item questionnaire that is widely used as a screening instrument. It provides a

measure of symptomatology for anxiety and depression, with cut-off scores based on normative population data.

In addition, participants also filled in two questions from the Pittsburgh Sleep Quality Index (Buysse et al 1989). The two questions form one component score, labelled “Daytime dysfunction”. Scores for the “Daytime dysfunction” represent a continuum with a range from 0 to 3; a higher score indicates more daytime dysfunction due to lethargy.

Procedure

Twelve patients registered with the identified practice were approached by their general practitioners and asked if they would consent to being contacted by the researcher to answer a number of questions about their use of benzodiazepine medication.

During a 4 to 6-week period the first three patients attending each general practitioner (for any reason), who were in receipt of a benzodiazepine prescription, were invited to participate in the pilot study; the selection process, therefore, was not strictly random. However, as the general practitioners were under instructions to approach the *first three* patients they encountered during the identified period of time, this helped to minimise selection bias. In addition, the general practitioners were blind to the exact questions that would be asked of their patients.

Of the twelve patients that were asked by their general practitioners to participate in the pilot study, nine agreed to meet with the researcher. Once consent had been given the researcher contacted each patient and arranged a home visit.

The amount of time spent with each participant varied from 40 to 60 minutes and was dependent on the volume of information volunteered by a participant during the semi-structured interview. The questionnaire items took between 5 and 10 minutes to complete.

Results

Stage One

Audit results

1. Number of patients (>16 years) registered with the identified practice who were in receipt of a repeat prescription for more than 3 months.

$N=147$

2. Type of benzodiazepine drug most frequently prescribed by the general practitioners and the number of patients prescribed each type.

Nitrazepam = 49	Lorazepam = 2
Temazepam = 59	Diazepam = 37

3. The ratio of male to female patients in receipt of benzodiazepine medication.

Females = 105	Males = 42
Ratio 2.5:1	

4. Type of benzodiazepine medication prescribed according to sex.

Table 1 reports the number of patients prescribed each type of benzodiazepine medication according to sex. Because over twice as many females as males were prescribed

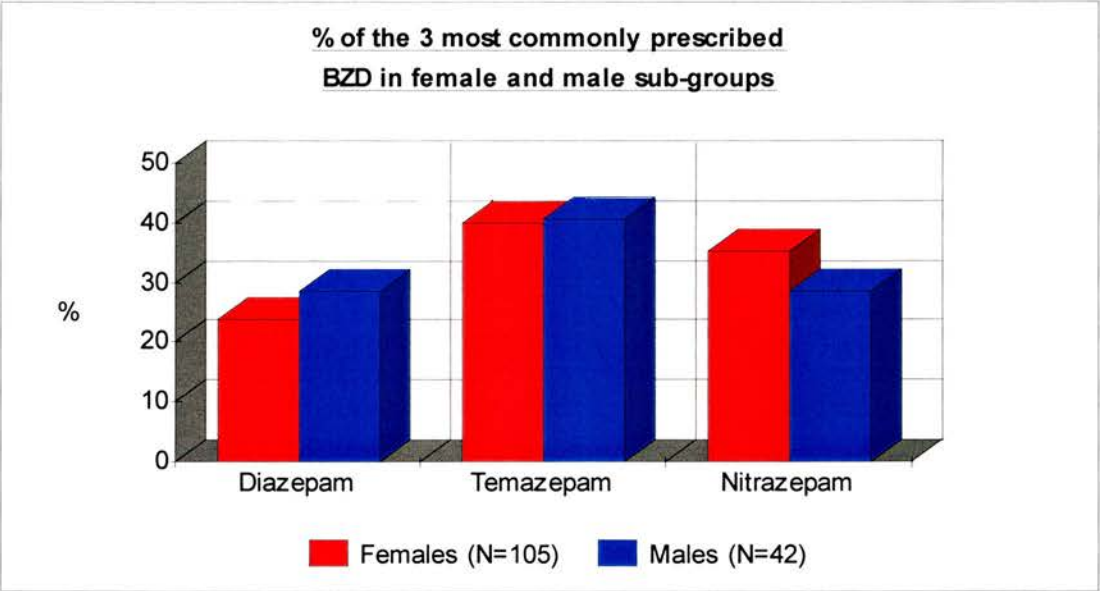
benzodiazepine medication, these figures are also presented as a percentage of the total number in each sub-group, this allows for comparison across the two groups.

Table 1: Distribution of four types of benzodiazepine medication according to sex

	Females		Males	
	<i>N</i>	% of females	<i>N</i>	% of males
Diazepam	25	23.8	12	28.57
Temazepam	42	40	17	40.47
Nitrazepam	37	35.23	12	28.57
Lorazepam	1	0.95	1	2.38
Total	105		42	

There would appear to be no significant difference with regard to the distribution of each type of benzodiazepine prescribed across the two groups.

Figure 1: Graph to show the percentage of each benzodiazepine (excluding lorazepam) prescribed according to female and male sub-groups



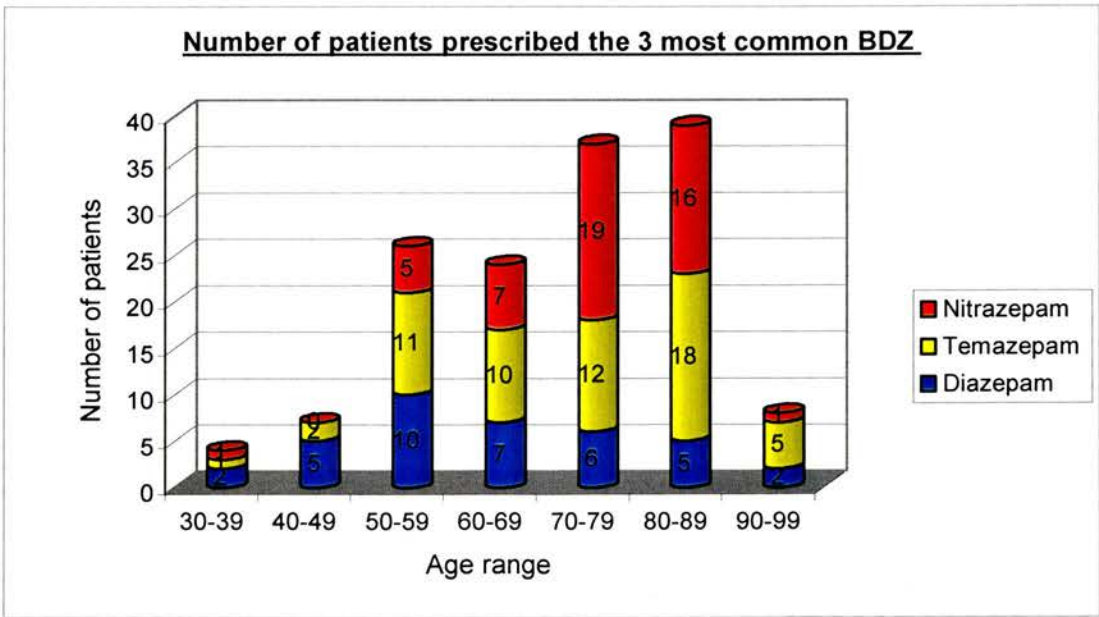
5. Number of patients and type of benzodiazepine medication prescribed according to age group.

Table 2 reports the number of patients prescribed each type of benzodiazepine medication according to age group. Total number of patients represented in Table 2 = 145; lorazepam data excluded.

Table 2: Distribution of the three most commonly prescribed benzodiazepine medication according to age range

	Age range (years)						
	30–39	40–49	50–59	60–69	70–79	80–89	90–99
No of patients on Diazepam	2	5	10	7	6	5	2
No of patients on Temazepam	1	2	11	10	12	18	5
No of patients on Nitrazepam	1	0	5	7	19	16	1
Total	4	7	26	24	37	39	8

Figure 2: Graph to show the number of patients prescribed benzodiazepine medication (excluding Lorazepam) according to age range



6. Number of patients in receipt of a repeat prescription according to individual general practitioners.

Table 3 reports the number of patients prescribed each type of benzodiazepine medication according to individual general practitioners. Data are also presented as a percentage of the total number of patients per doctor; this allows for comparisons between the four doctors.

There are a number of obvious problems when comparing the prescribing patterns of individual general practitioners; these are highlighted in the discussion. Nevertheless, the purpose of examining these data was simply to consider (i) whether the general practitioners were all prescribing benzodiazepine medication to a similar extent, and (ii) whether individual general practitioners favoured certain benzodiazepine medication to the exclusion of other types.

Table 3: Distribution of each benzodiazepine medication according to individual general practitioner

	Doctor A		Doctor B		Doctor C		Doctor D	
	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%
Diazepam	7	17.5	10	27.07	16	32	4	20
Temazepam	22	55	13	35.13	13	26	11	55
Nitrazepam	9	22.5	14	37.83	21	42	5	25
Lorazepam	2	5						
Total	40		37		50		20	

Doctors’ A and D have a greater percentage of their patients in receipt of temazepam medication. Doctors’ B and C have a greater percentage of their patients in receipt of nitrazepam medication. Nevertheless, it does not appear that any of the general practitioners favour the prescribing of one benzodiazepine to the exclusion of all others.

7. Length of time patients (*N*= 147) have been in receipt of repeat prescription.

Mean no. of years = 5.30 (SD 4.65)

Figure 3: Graph to show the length of time patients have been in receipt of their BZD prescription.

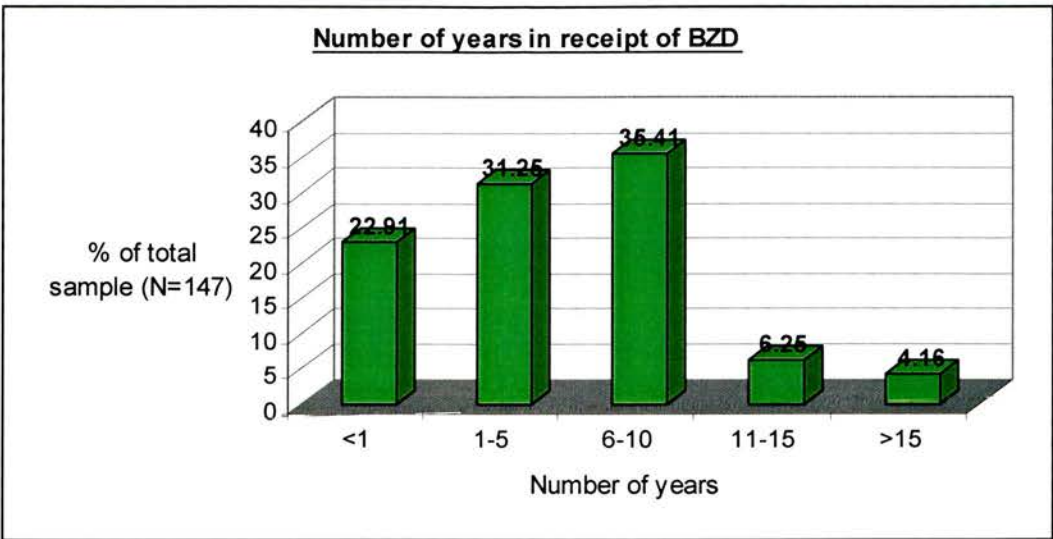


Figure 3 illustrates that the largest grouping: 35 per cent of the sample have been taking their benzodiazepine medication for between 6 and 10 years. The second largest grouping are those patients who have been taking their benzodiazepine medication for between 1 and 5 years; this group forms 31 per cent of the sample.

Stage Two

Questionnaire

Table 4 reports participants' questionnaire scores for HADS and the Pittsburgh Sleep Quality Index (PSQI) – daytime dysfunction score.

The HADS provides both an anxiety score (range 0–21) and a depression score (range 0–21); with higher scores indicating the presence of more symptomatology. HADS scores for each condition are grouped in four categories of severity:

0-7 = normal 8-10 = mild 11-14 = moderate 15-21 = severe

Table 4 also includes each participants' daytime dysfunction score (range 0–3) derived from two questions in the PSQI. A higher score indicates an increase in daytime dysfunction due to lethargy.

Table 4: HADS and PSQI scores for nine benzodiazepine users

Participant	Anxiety score	Depression score	Day-time dysfunction score
1	8*	7	1
2	3	6	0
3	5	1	0
4	5	2	0
5	5	5	1
6	8*	4	1
7	4	1	1
8	20*	8*	1
9	9*	7	2

(* = above cut off)

Table 4 shows that four of the nine participants had significant scores for either anxiety or depression. Three participants demonstrate mild anxiety and participant number 8 demonstrated severe anxiety and mild depression. With the exception of participant 9, daytime dysfunction appears to be minimal.

Semi-structured interview data

The purpose of the semi-structured interview was to collect a range of qualitative information from the nine long-term benzodiazepine users. Information volunteered by the participants varied considerably in content and was therefore difficult to quantify and categorise.

However, each participants discourse included responses to a number of predetermined questions. A brief synopsis of these individual responses can be found in the Pilot study

appendix. Below, a general summary of the nine individual synopses found in the Pilot study appendix is given.

Bereavement, health anxiety and stress were the most commonly reported problems which led to the patient consulting their general practitioner. In almost every case the patient presented to their general practitioner as having sleep difficulties as a result of these problems and a repeat prescription for a benzodiazepine medication was given.

Four patients were in receipt of temazepam, three patients were in receipt of nitrazepam and two patients were in receipt of diazepam. Interestingly the three patients taking nitrazepam each reported experiencing the "hangover effect". Two of the three had found this had previously interfered with their work performance (they were still in employment at the time) and they had subsequently revisited their general practitioners which had resulted in a dosage reduction. Following participation in the research, the third patient (Participant 9 in Table 4) consulted his general practitioner about feeling "sleepy" in the mornings and was transferred on to a prescription for temazepam. With the exception of one patient, who found that benzodiazepine medication affected bowel movement, there were no other reported side-effects.

Only one patient reported that the effectiveness of their medication reduced over time. However, two patients described their use of benzodiazepine medication to be "infrequent" (one or two nights a month) and another patient said that he deliberately chose to take his benzodiazepine on alternate nights to avoid "getting too used to it"

With the exception of participant 5, all participants reported sleeping an average of 4–5 hours per night. The sample divided equally into two groups; those that fell to sleep easily and those that found that it took them a long time to fall asleep. There was no association between length of time taken to get to sleep and psychopathology, as measured by the

HADS. Also, there did not appear to be a link between difficulty in falling to sleep and length of time on benzodiazepine medication. For example, of the four participants that reported it took them a long time to get to sleep, two had been taking benzodiazepine medication for over 10 years; in contrast, the other two participants had been taking benzodiazepine medication for 1 year. This is a worthwhile line of inquiry because prescribing guidelines suggest that the efficacy of benzodiazepine medication diminish over time. Despite half the sample complaining that it took them a long time to get to sleep, they did not appear to perceive this as an indication that their medication was not very effective. Instead, they all believed that without any medication at all they would sleep for fewer hours.

Of those four participants that reported less difficulty in getting to sleep, three did not take their benzodiazepine medication every day and the fourth participant (participant 7) in this group exceeded his prescribed dosage most nights. Interestingly these four participants were all using temazepam. The remaining five participants in the sample (of whom four reported difficulty in getting to sleep) were all prescribed nitrazepam or diazepam medication.

When the participants were asked how much they felt that they needed to take their medication they all denied "addiction" with regard to their benzodiazepine use. The three "infrequent" users each suggested that they could not be dependent/addicted because they did not take their tablets every night. Of the remaining six participants that took their medication every day, three said that they "must be dependent" because they needed their tablets to get to sleep. A further two participants said that they "needed" to take their tablets every night to get to sleep, but that they were not "dependent" or "addicted" to them. Finally, one participant said that their benzodiazepine was a "habit" but that she was not "dependent on them"

Five participants said that they did not want to consider stopping or reducing their benzodiazepine use. Of the four that said they would consider stopping their benzodiazepine use, two said that they would not seek help with this – they said that they would prefer to stop by themselves. Two participants said that they thought the first step if they decided to stop taking their benzodiazepine would be to speak to their general practitioner.

Discussion

In summary, audit of repeat prescriptions for benzodiazepine in a small rural practice found 2.94 per cent of the total practice population over the age of 16 years to be in receipt of a prescription for benzodiazepine medication. Approximately two-thirds of this sample were over 65 years old.

In line with the claim made by Hawley (1994) who said that there has been a decline in the prescribing of anxiolytic medication, whilst prescribing rates for hypnotics have remained constant, the vast majority of the sample would appear to be prescribed benzodiazepines for sleep difficulties.

The audit found the ratio of female to male prescribed benzodiazepines was two and a half females per male. This is a predictable finding for two reasons, firstly it is generally felt that women are far more likely than men to present to their general practitioners and talk about their worries (Butler & Hope 1995). Secondly, as women tend to live longer than men, the ratio of females to males is naturally higher in the elderly population.

With the exception of two cases, where lorazepam was prescribed, the general practitioners used the same three benzodiazepine drugs for all cases requiring an anxiolytic or hypnotic. Prescribing patterns of individual general practitioners did not significantly differ. It is also important to bear in mind that some general will have "inherited" patients already in receipt of a repeat prescription. Also, of the four general practitioners only one was female (part-

time). It is therefore possible that she would have a higher proportion of female patients, who as mentioned already, are more likely to present with problems that lead to the general practitioners prescribing benzodiazepine medication. In addition, one of the general practitioners had been with the practice considerably longer than the other three. This general practitioner was more likely to have a greater number of elderly patients.

Questionnaire data and semi-structured interviews with nine long-term benzodiazepine users found the following features. Almost half the sample (45 per cent) were found to demonstrate a significant degree of anxiety and or depression, as measured by the HADS. A higher incidence of anxiety compared with depression was found, although caution should be exercised because, with the exception of one participant, scores were "borderline" with regard to clinical significance.

Participants that were prescribed the longer-acting benzodiazepine, nitrazepam, reported "hang-over" effects.

With the exception of one participant, those participants prescribed temazepam took their medication less frequently than the rest of the sample (who used their medication every day). These three participants reported that they were prepared to accept some sleeplessness when they did not take their tablets, as they knew they could "fall back on" their medication when they felt they "really needed it". It was interesting to note that of the six participants' that took their medication every day, only one was using a short-acting benzodiazepine (temazepam), the other five participants were prescribed the long-acting benzodiazepines nitrazepam and diazepam.

In general, the sample were reluctant to consider that they were "dependent" or "addicted", although a small number volunteered the word "dependent", the word "addicted" was vigorously denied by all participants.

Of the sample of participants that were asked if they would like to stop using their benzodiazepine medication, less than 50 per cent were prepared to consider the option. This

finding is comparable with published research (Wright et al 1994, Linden et al 1998). The only reason participants gave for this was because they felt that they would not get any sleep without their tablets.

Implications for the main study

It is not possible to draw definitive conclusions from the information gathered in the pilot study. Nevertheless, the data collected informed the choice of standardised measures chosen for the larger study.

Firstly, as a result of the pilot study, it was felt that the HADS might not be a sensitive enough measure for use with the larger sample. This was because the audit information revealed that the potential sample for the larger study would consist of a large majority of older adults. There exists some research evidence which argues that the HADS is a less accurate measure of anxiety and depression in older adults (Kenn et al 1987, Flint and Rifat 1996, Davies et al (1993). However, the use of the HADS with the nine participants in the pilot study, did elicit the presence of some anxiety and depressive symptomatology in the sample and therefore confirmed the validity of assessing for depression and anxiety in this group of patients.

Secondly, the pilot study demonstrated that individual use of benzodiazepine medication was mostly attributed to sleep difficulties. Therefore, the use of a comprehensive measure of sleep quality would be important for use with the larger sample. Also, dialogue with the small sub-sample revealed that whilst sleep difficulties were found to be the common presenting problem, which prompted the prescription for benzodiazepine medication, the participants disclosed a range of different problems as the "cause" of their sleep difficulties. This finding informed the decision to include a standardised measure that was designed to screen for a number of clinical disorders.

Thirdly, the pilot study revealed an interesting and potentially important difference within the sample. A proportion of those patients in receipt of a repeat prescription did not take their medication on a daily basis. These participants reported that they preferred not to take their tablets unless they felt it was completely necessary, for example if they had not had "enough" sleep in the preceding nights. One participant described his tablets as an "insurance policy". An important part of the larger study would be to explore what (if any) is the difference between patients that choose not to take their tablets daily and those that do take them every day. It would therefore be meaningful to include measures that would assess subject variables in addition to psychopathology. One option might be to consider a patient's use of alternative resources to that of pharmacology, for example psychological resources (psychological mindedness). A further variable to consider is that of (perceived) dependence on benzodiazepine medication.

In summary, the pilot study used both audit data ($N = 147$) and qualitative data ($N = 9$): these data provided a good starting point with regard to informing which variables would be important to consider in the larger study.

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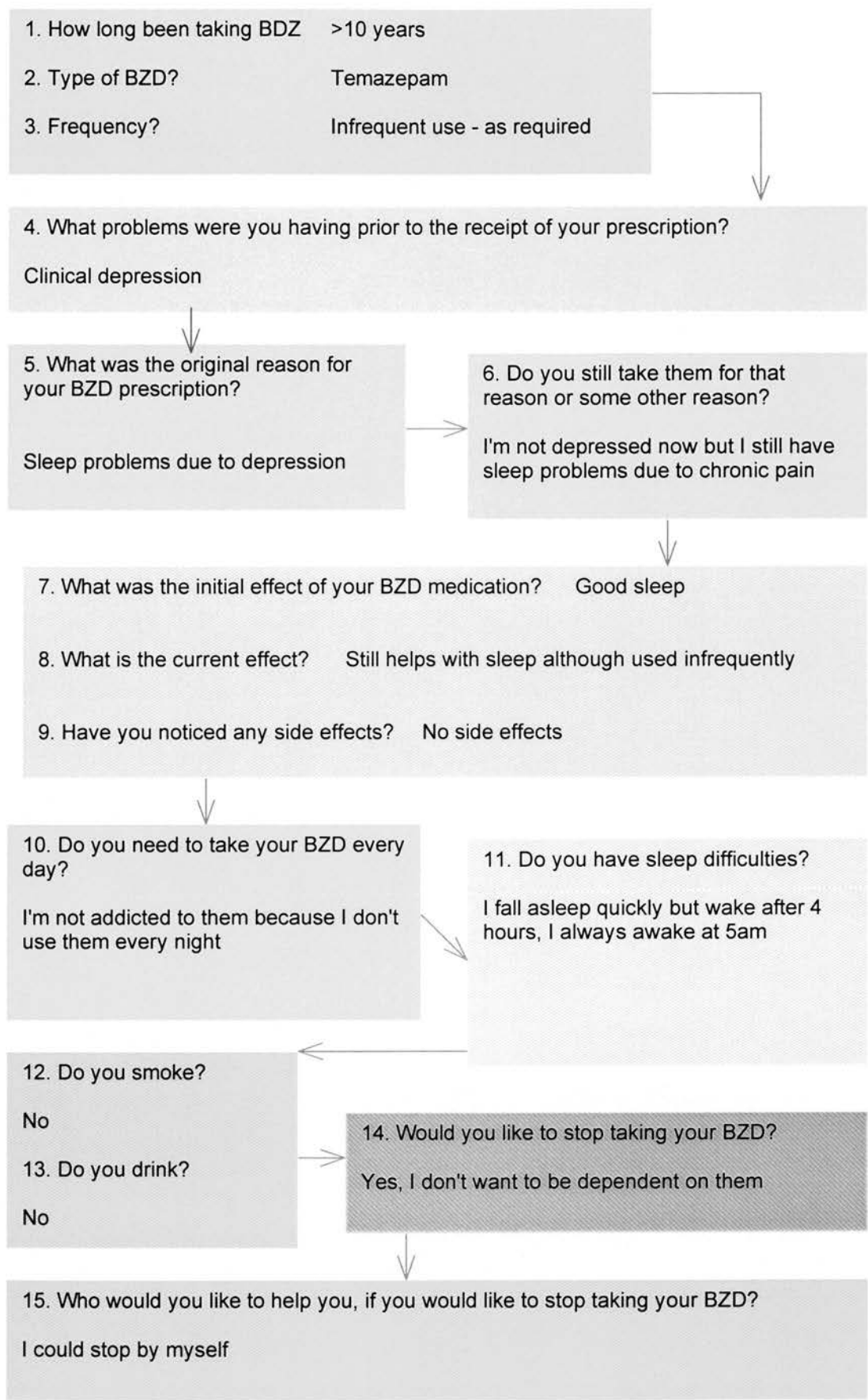
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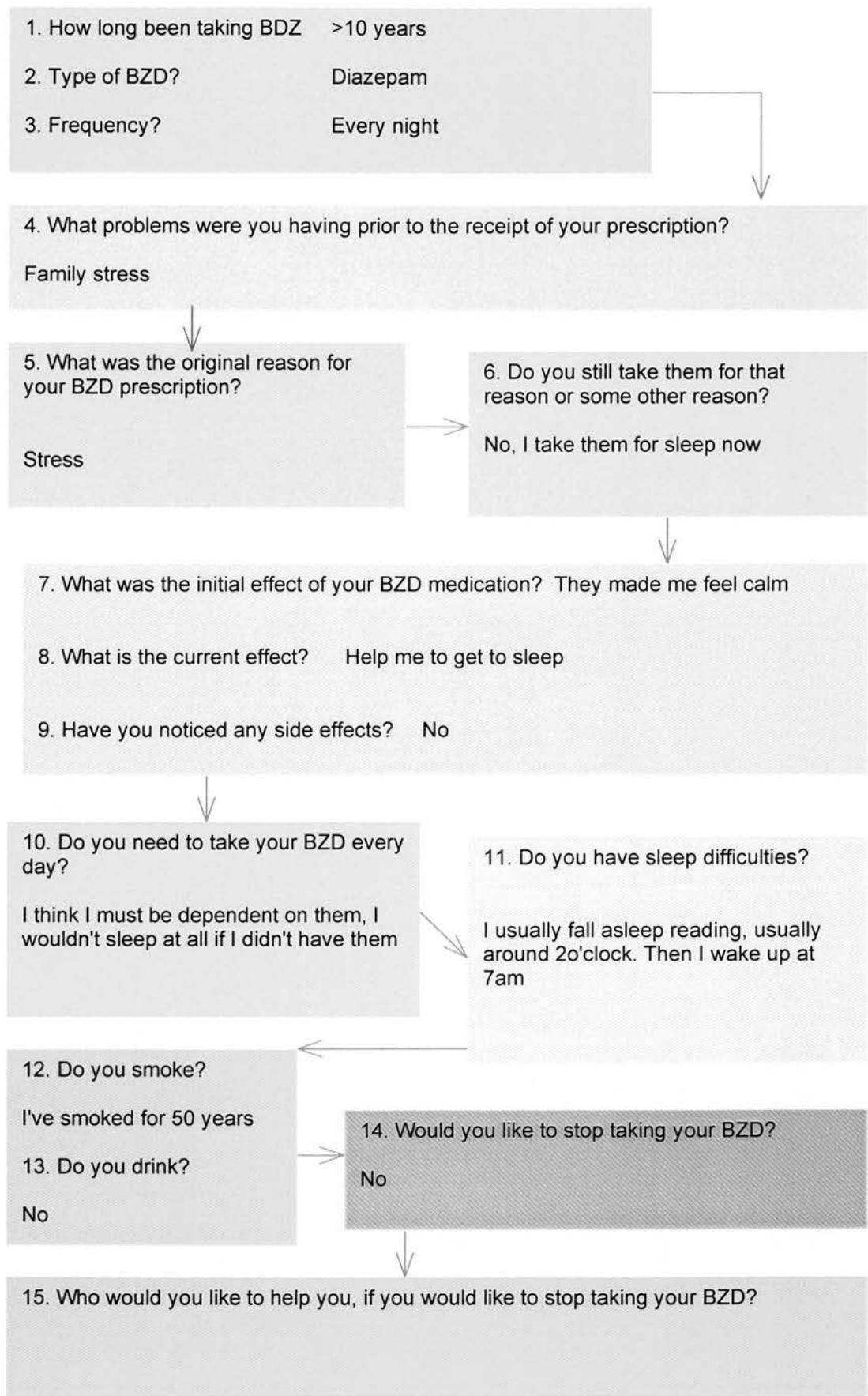
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Pilot Study: Appendix

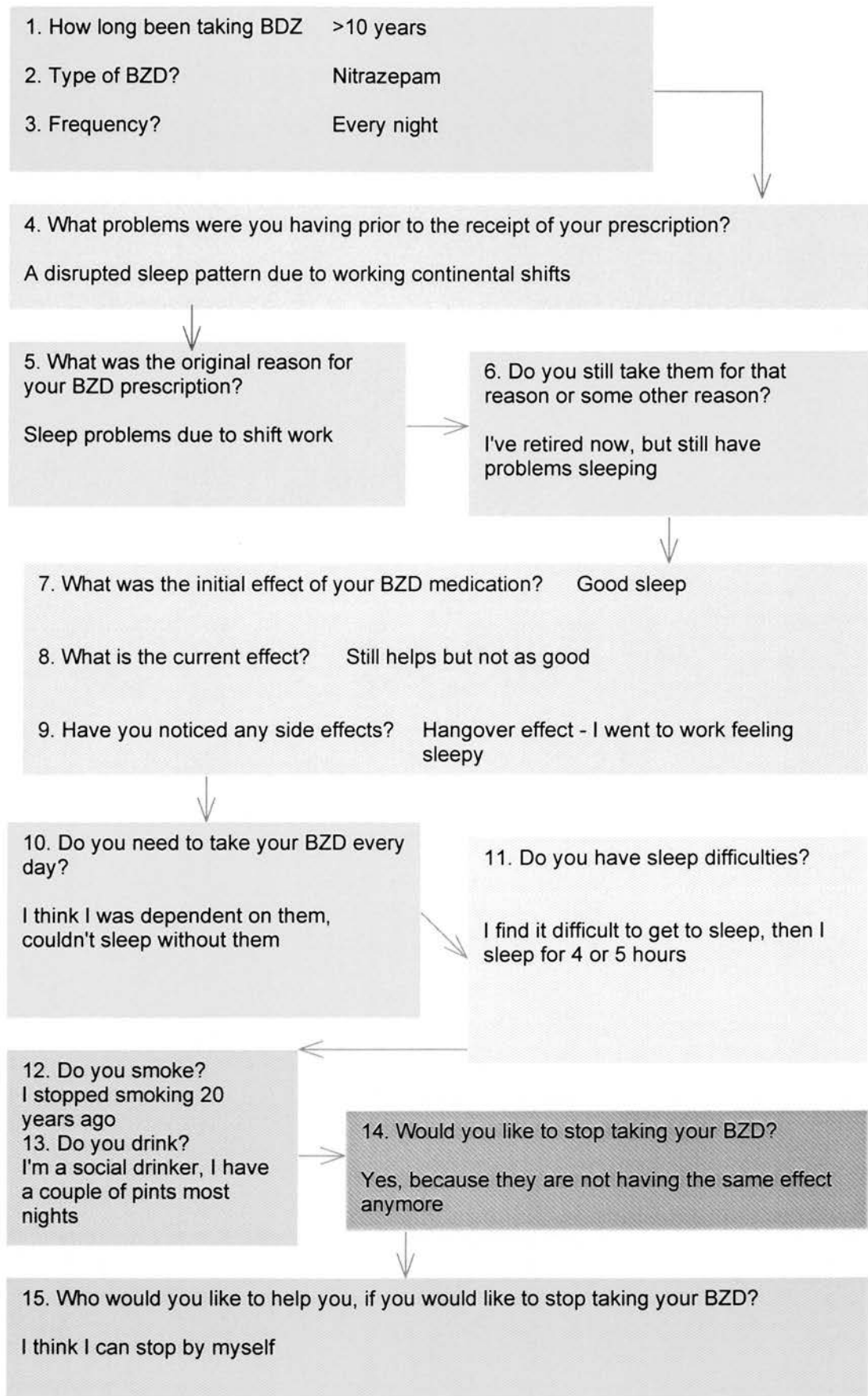
Participant 1



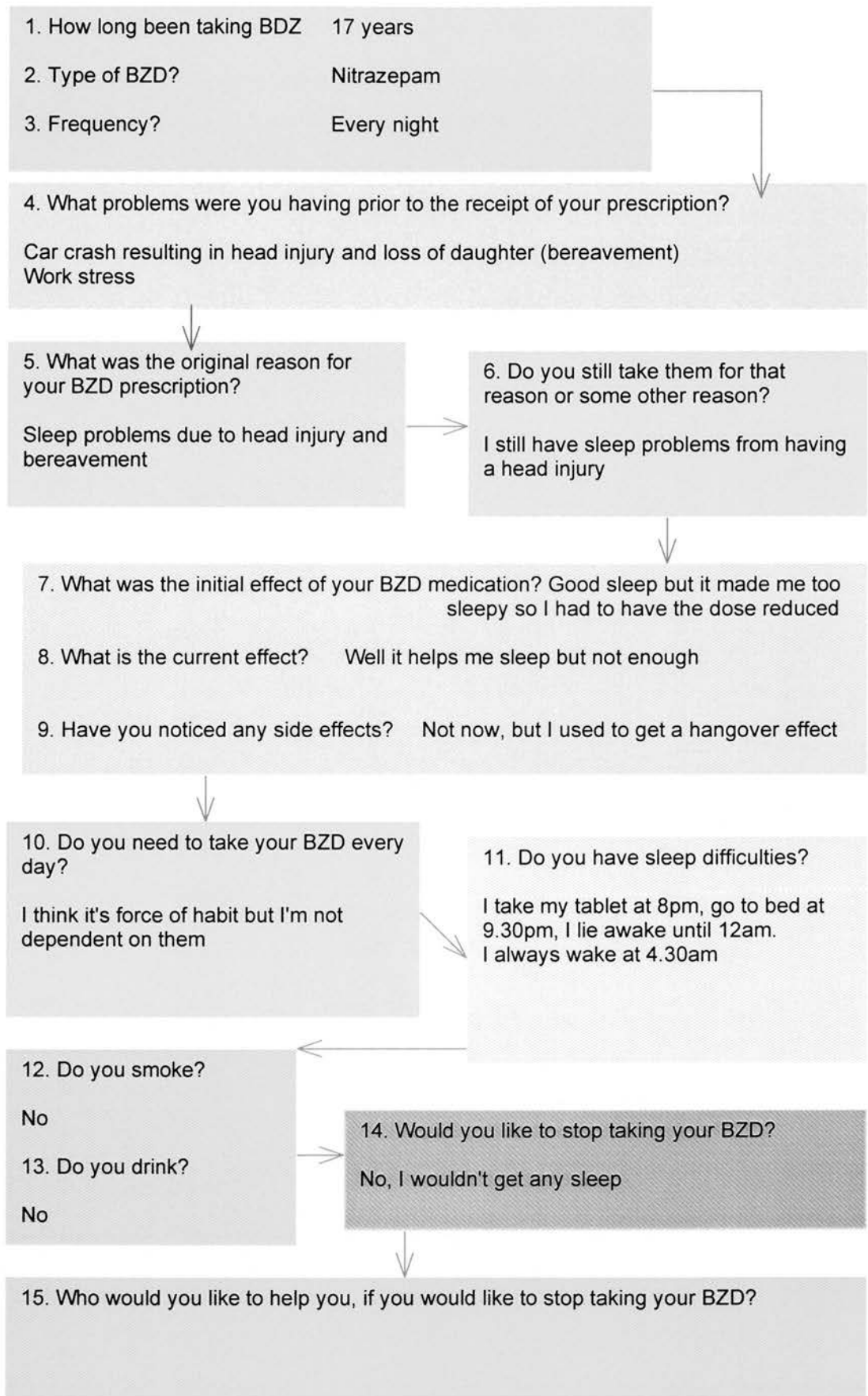
Participant 2



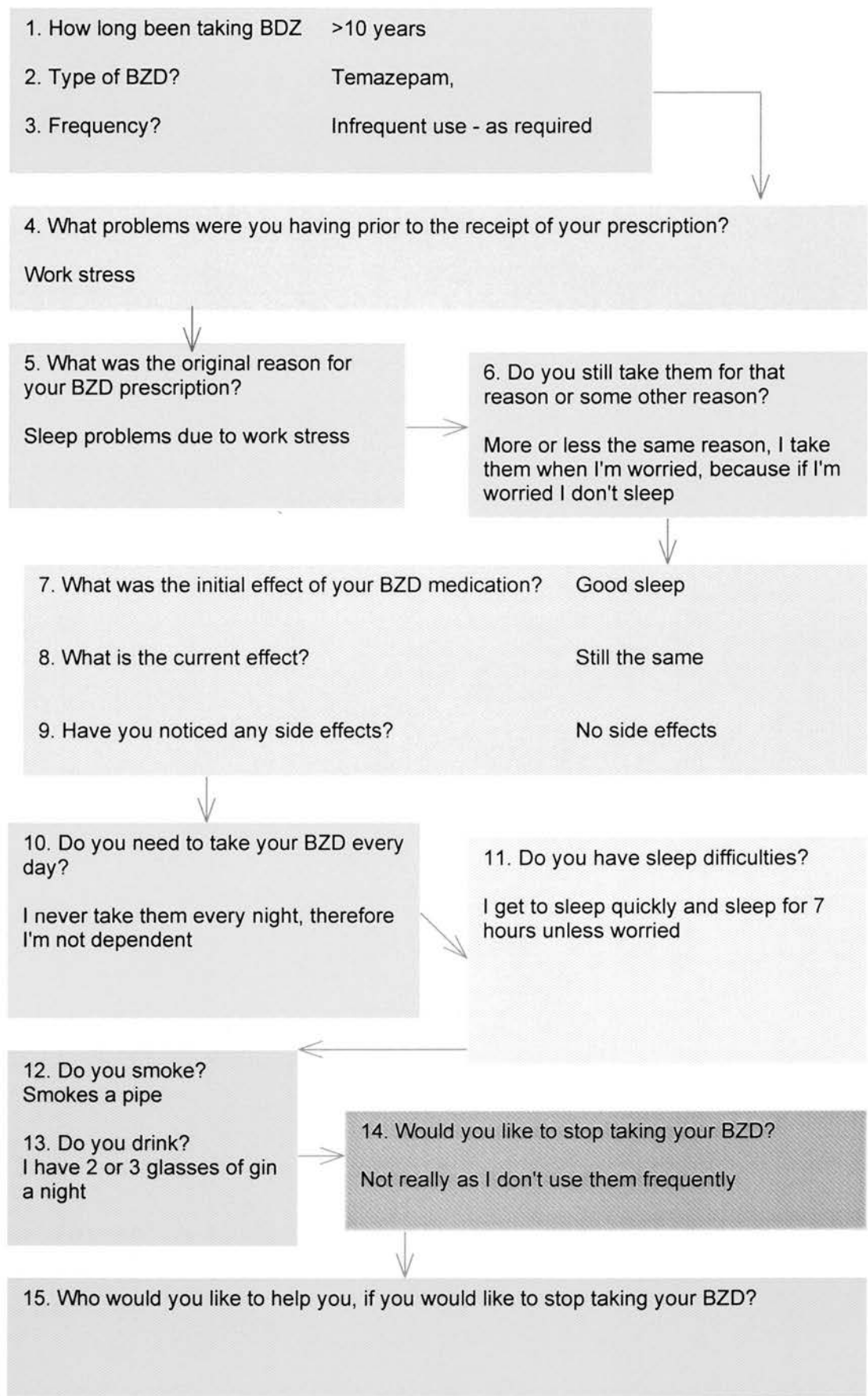
Participant 3



Participant 4



Participant 5



Participant 6

1. How long been taking BDZ?	15 years
2. Type of BZD?	Temazepam
3. Frequency?	Several nights per week

↓

4. What problems were you having prior to the receipt of your prescription?
Heart by-pass operation

↓

5. What was the original reason for your BZD prescription?	6. Do you still take them for that reason or some other reason?
Sleep problems due to medication given for cardiac problems	Same reason

↓

7. What was the initial effect of your BZD medication?	Helped with sleep but effectiveness soon wore off
8. What is the current effect?	Not that helpful
9. Have you noticed any side effects?	Interfered with bowel movement

↓

10. Do you need to take your BZD every day?	11. Do you have sleep difficulties?
I've never felt addicted, because I try not to take them every day.	I get to sleep quickly but wake after 2 or 3 hours. I lie awake until 5am when I fall back to sleep for 2 or 3 hours

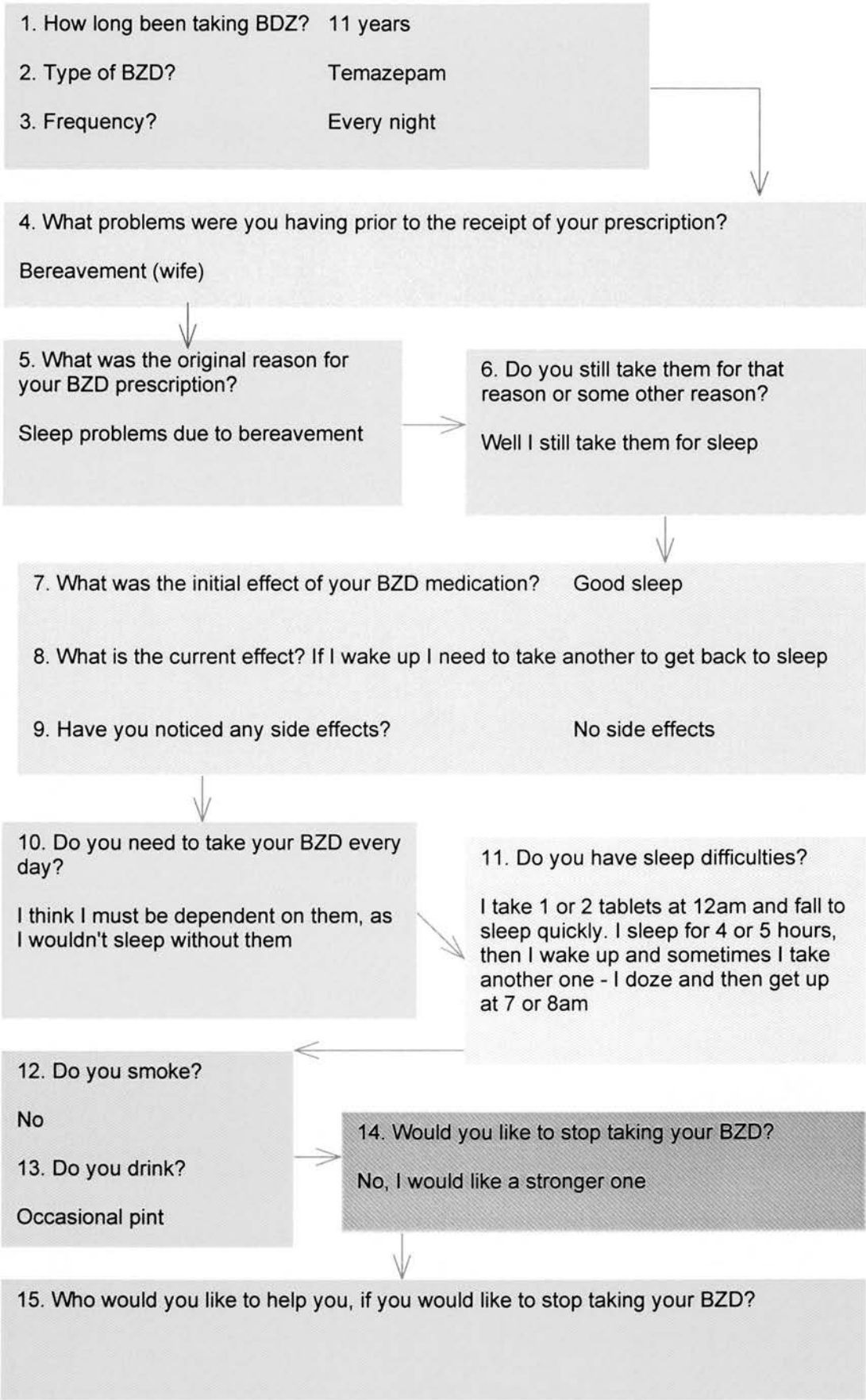
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12. Do you smoke?	14. Would you like to stop taking your BZD?
No	Yes, I would like to be able to get to sleep without them
13. Do you drink?	
I have an occasional drink	

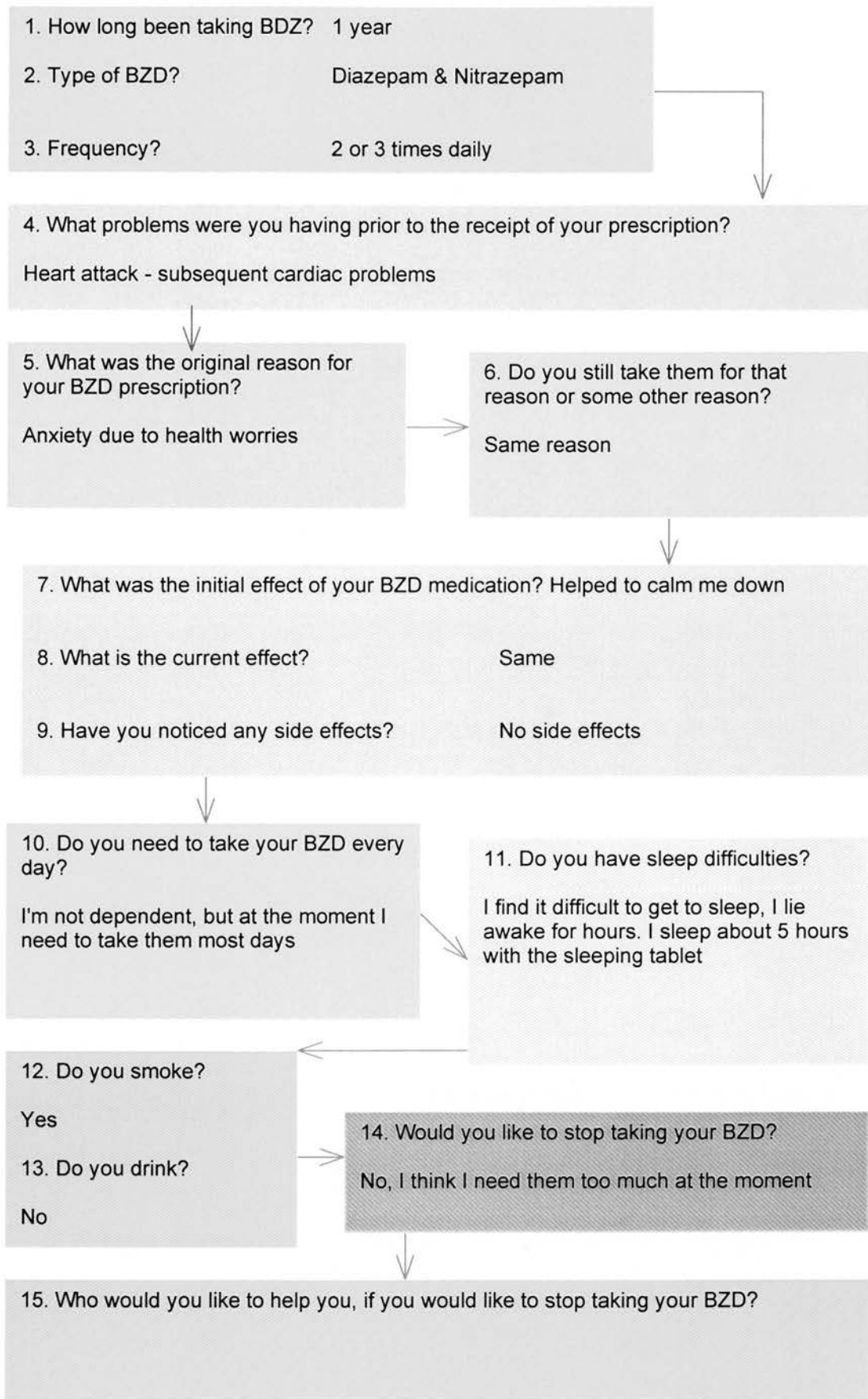
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15. Who would you like to help you, if you would like to stop taking your BZD?
I suppose my GP

Participant 7



Participant 8



Participant 9



APPENDIX 2

Semi-structured interview schedule

Study questionnaire

Name

D.O.B

Marital status *(If living alone ask for how long)*

Employment status *(If not working ask when stopped)*

How long have you been in receipt of your prescription?

Do you take your tablets as prescribed by your doctor? For example is that everyday or just at certain times? If at certain times when would that be?

What was the original reason you were prescribed benzodiazepine medication?

Can you remember who gave you your first prescription?
If yes - who?

Yes ☐

No ☐

What is the current reason(s) for your use of benzodiazepine medication? *(If more than one reason rate)*

Do you drink alcohol?

Yes ☐

No ☐

If yes - how much? For example what would you drink in an average week.

If you drank more alcohol in the past was it ever a problem? For example do you think you ever drank too much?

Do you smoke cigarettes?

Yes ☐

No ☐

If yes - how many?

How long have you smoked?

If you smoked in the past when and why did you stop?

How long did you smoke for?

Name

Do you have any medical health problems?

If yes - are you taking any medication?

Do you have any painful conditions?

If yes - what? how long? pain relief?

Would you like to stop or reduce your BZD tablets?

Yes ☐

No ☐

If yes - what help do you think you would need? For example who do you think could help?

If no - what are your reasons for not wanting to change you current use of BZD?

Is there anything else I should have asked you? Is there anything you would like to add?

Give info leaflet then say: After you have had a chance to read the leaflet you might decide you would like to find out more about stopping your tablets. Please return the slip in the leaflet if you like to find out more.

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the **majority** of days and nights in the **PAST MONTH**.

For each of the remaining questions, tick the one best response.

During the past month, how often have you had trouble sleeping because you.....	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
Cannot get to sleep within 30 minutes				
Wake up in the middle of the night or early morning				
Have to get up to go to the bathroom				
Cannot breathe comfortably				
Cough or snore loudly				
Feel too cold				
Feel too hot				
Had bad dreams				
Have pain				
Other reason(s), please describe.....				
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
How often during the past month have you had trouble sleeping because of this other reason				
During the past month, how often have you take medicine (prescribed or "over the counter") to help you sleep?				
During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				

PLEASE ANSWER ALL QUESTIONS.

	Very good	Fairly good	Fairly bad	Very bad
During the past month, how would you rate your sleep quality overall?				
	No problem at all	Only a slight problem	Somewhat of a problem	A very big problem
During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?				

Below is a list of problems people sometimes have. Please read each one carefully, and tick the response that best describes **HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST 7 DAYS INCLUDING TODAY.**

BRIEF SYMPTOM INVENTORY



HOW MUCH WERE YOU DISTRESSED BY:	Not at all	A little bit	Moderately	Quite a bit	Extremely
Nervousness or shaking inside					
Fainting or dizziness					
Pains in heart or chest					
Feeling afraid in open spaces or in the streets					
Thoughts of ending your life					
Suddenly scared for no reason					
Feeling lonely					
Feeling blue					
Feeling no interest in things					
Feeling fearful					
Your feelings being easily hurt					
Feeling that people are unfriendly or dislike you					
Nausea or upset stomach					
Feeling inferior to others					
Feeling afraid to travel on buses, subways or trains					
Trouble getting your breath					
Hot or cold spells					
Having to avoid certain things, places or activities because they frighten you					
Numbness or tingling in parts of your body					
Feeling hopeless about the future					
Feeling weak in parts of your body					
Feeling tense or keyed up					
Feeling very self-conscious with others					
Feeling uneasy in crowds, such as shopping					
Spells of terror or panic					
Feeling nervous when you are left alone					
Feeling so restless that you couldn't sit still					
Feelings of worthlessness					

PLEASE ANSWER ALL QUESTIONS.

Please place a tick next to the response which best describes how you have felt during the **PAST MONTH** about your tranquillisers (benzodiazepine medication).

	Never/ almost never	Sometimes	Often	Always/ nearly always
Did you think your use of tranquillisers was out of control?				
Did the prospect of missing a dose make you anxious or worried?				
Did you worry about your use of tranquillisers?				
Did you wish that you could stop?				
	Not difficult	Quite difficult	Very difficult	Impossible
How difficult would you find it to stop or go without your tranquillisers?				

Please place a tick next to the response which best describes how you feel about each of the following statements.

	Strongly Agree	Mostly Agree	Mostly Disagree	Strongly Disagree
I would be willing to talk about my personal problems if I thought it might help me or a member of my family.				
I am always curious about the reasons people behave as they do.				
I think that most people who are mentally ill have something physically wrong with their brain.				
When I have a problem, if I talk about it with a friend, I feel a lot better				
Often I don't know what I'm feeling.				
I am trying to change old habits to try a new way of doing things.				
There are certain problems which I could not discuss outside my immediate family.				
I often find myself thinking about what made me act in a certain way.				
Emotional problems can sometimes make you physically sick.				

PLEASE ANSWER ALL QUESTIONS.

	Strongly Agree	Mostly Agree	Mostly Disagree	Strongly Disagree
When you have problems, talking about them with other people just make them worse.				
Usually, if I feel an emotion, I can identify it.				
If a friend gave me advice about how to do something better, I'd try it out.				
I am annoyed by someone, whether he is a doctor or not, if they want to know about my personal problems.				
I find that once I develop a habit it is hard to change, even if I know there is another way of doing things that might be better.				
I think that people who are mentally ill often have problems that begin in their childhood.				
Letting off steam by talking to someone about your problems often makes you feel a lot better.				
People sometimes say that I act as if I'm having a certain emotion (anger for example) but I am unaware of it.				
I get annoyed when people give me advice about changing the way I do things.				
It would not be difficult for me to talk about personal problems with people such as doctors and clergymen.				
If a good friend of mine suddenly started to insult me, my first reaction might be to try to understand why he was so angry.				
I think that when a person has crazy thoughts, it is often because he is very anxious or upset.				
I've never found that talking to other people about my worries helps much.				
Often, even though I know that I'm having an emotion, I don't know what it is.				

PLEASE ANSWER ALL QUESTIONS.

	Strongly Agree	Mostly Agree	Mostly Disagree	Strongly Disagree
I like to do things the way I've done them in the past. I don't like to try and change my behaviour much.				
There are some things in my life that I would not discuss with anyone.				
Understanding the reasons you have deep down for acting in certain ways is important.				
At work, if someone suggested a different way of doing a job that might be better, I'd give it a try.				
I've found that when I talk about my problems to someone else. I come up with ways to solve them that I hadn't thought of before.				
I am sensitive to the changes in my own feelings.				
When I learn a new way of doing something, I like to try it out to see if it would work better than what I have been doing before.				
It is important to be open and honest when you talk about your troubles with someone you can trust.				
I really enjoy trying to figure other people out.				
I think that most people with mental problems have probably received some kind of injury to their head.				
Talking about your worries to another person helps you to understand your problems better.				
I'm usually in touch with my feelings.				
I like to try new things, even if it involves taking risks.				
It would be very difficult for me to discuss upsetting or embarrassing aspects of my personal life with people even if I trust them.				
If I suddenly lost my temper with someone, without knowing exactly why, my first impulse would be to forget about it.				
I think that a person's environment (family etc) has very little to do with whether he develops mental problems.				
When you have some troubles, talking about them to someone else just makes you more confused.				
I frequently don't want to delve too deeply into what I'm feeling.				

PLEASE ANSWER ALL QUESTIONS.

	Strongly Agree	Mostly Agree	Mostly Disagree	Strongly Disagree
I don't like doing things if there is a chance that they won't work out.				
I think that no matter how hard you try, you'll never really understand what makes people tick.				
I think that what goes on deep down in a person's mind is important in determining whether he will have a mental illness.				
Fear of embarrassment or failure doesn't stop me from trying something new.				

(Note: The format and font size of this questionnaire has been reduced to fit margins)

APPENDIX 3

BORDERS RESEARCH ETHICS COMMITTEE

Response for a local research proposal

Copy to be sent to the local researcher

1. LREC name and address	Borders Research Ethics Committee Trust Management Borders General Hospital NHS Trust Melrose Roxburghshire TD6 9BS
2. Title of study	Benzodiazepine use in a primary care population
3. Name of local researcher	April Quigley, Trainee Clinical Psychologist, Psychological Therapies Services, Borders Primary Care NHS Trust
4. LREC reference number	02/BREC/03

Borders Research Ethics Committee has considered the above application with a view to recommending whether the research should go ahead locally.

5. Borders Research Ethics Committee considered the following issues:

	approve	defer	reject
Suitability of researcher and support staff	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Suitability of site	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Suitability of research for local subject population	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient information sheet and consent form (please state)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If any of the above are deferred or rejected, please state reason.

6. Borders Research Ethics Committee wishes to offer the following comments for information

Copies of the GP letter and information sheet must be forwarded to the Committee once they have been finalised.

7. Borders Research Ethics Committee wishes to raise the following significant concerns

Date application considered

17th January 2002

Process by which application was considered locally:

full committee

The decision of Borders Research Ethics Committee

- ☒ Borders Research Ethics Committee recommends the research go ahead. Please read the conditions of approval attached to this form
- ☐ Borders Research Ethics Committee does not recommend the research go ahead for the local reasons set out in 7.
- ☐ Borders Research Ethics Committee has deferred making a decision and is awaiting clarification from the research

Signed Chairman/Representative of
Borders Research Ethics Committee

Date

23.1.02

Print name

Mr A.C.H. Watson, Chairman

APPENDIX 4

Copy of recruitment letter from GP's

Copy of return slip

Copy of second recruitment letter from researcher

HEADED PAPER

DATE

«FirstName» «LastName»

«Address1»

«Address2»

«City»

«PostalCode»

Dear «FirstName»

We are fortunate to have as part of the team in the Practice at the moment Dr April Quigley who is a trainee Clinical Psychologist. She is interested to do some research in to the use of Benzodiazepine medication.

Benzodiazepine tablets include Diazepam, Temazepam and Nitrazepam tablets. These tablets are usually prescribed for sleep and anxiety problems. As you have a prescription for this type of medication she would very much like to meet with you (even if you are not currently taking them).

Dr Quigley is happy to arrange a meeting with you either at the Health Centre or at your home and obviously involvement in the study is entirely voluntary. This meeting will involve answering a few questions about your tablets and filling in a questionnaire.

May we reassure you that participation in this study will not affect your prescription in any way and also that any information gathered will be kept entirely confidential and will be destroyed after the study is completed.

Should any patient decide that they would like to stop or reduce their Benzodiazepine tablets Dr Quigley will be able to offer some psychological help with this.

You will find enclosed with this letter a return slip, we would very much appreciate it if you could fill this in and return it in the S.A.E. provided.

Trusting that you will consent to be contacted, in receipt of your reply Dr Quigley will be in touch in due course. You will then have the opportunity to ask any questions you might have and if you choose to participate Dr Quigley will arrange a meeting with you.

If you agree to participate in this study it will not affect you current prescription and the study will ensure complete anonymity and confidentiality.

At any time you may change your mind and withdraw from the study.

Many thanks for your help in this valuable piece of research.

Yours sincerely

Dr.....(relevant GP)

This study has been approved by the Borders Research Ethics Committee

Benzodiazepine study

Name

I would be happy for April Quigley to contact me about the study:

Yes

Tick one

☐

No

☐

(Note: ticking “yes” does not mean you are agreeing to take part, just that you are willing to be approached.)

I am happy to be contacted by:

Letter or telephone

Tick one

☐

Just by letter

☐

This study has been approved by the Borders Research Ethics Committee

HEADED PAPER

DATE

«FirstName» «LastName»
«Address1»
«Address2»
«City»
«PostalCode»

Dear «FirstName»

You may remember receiving a letter from your GP asking you to take part in a study we are currently undertaking in Jedburgh which is looking at Benzodiazepine medication. First of all I would like to thank you for returning your slip on which you indicated that you would prefer to be contacted by letter.

If you would agree to meet with me I would like to visit you at home or you may chose to come along to the Health Centre.

The meeting would involve answering some questions about your tablets, for example, do they help and in what way, and questions about your sleep and any health problems or worries you might have.

The study is like a survey and all the information we gather from the people we speak to remains anonymous. I have seen a number of people so far who have all said that the questions were not intrusive and that they had been pleased to help.

Could I ask you to return the enclosed slip in the S.A.E. provided, which offers a choice of times when one of us could meet with you.

In anticipation of your help thank you very much.

Yours sincerely

Ms April Quigley
Trainee Clinical Psychologist

APPENDIX 5: ADDITIONAL RESULTS

Appendix 5 (a)

Medical conditions and benzodiazepine use

Table 1: Prevalence of medical conditions according to sex

Appendix 5 (b)

Reasons given for benzodiazepine use

Figure 1: Reason given for original benzodiazepine prescription

Figure 2: Reason given for current use of benzodiazepine

Appendix 5 (c)

Correlation matrix for SDS items

Appendix 5 (d)

The Pittsburgh Sleep Quality Index

Table 2: Correlation matrix to show the relationship between BSI dimension scores and

Figure 3: Error bar chart to show mean scores on 7 components of PSQI & 95% CI

Figure 4: Sleep latency: distribution of number of minutes taken to fall asleep

Figure 5: Sleep duration: total number of hours slept per night

APPENDIX 5: ADDITIONAL RESULTS

Appendix 5 (a)

Medical conditions and benzodiazepine use

Table 1 below reports the number of participants in receipt of medication for each of the 8 categories of medical conditions grouped according to BNF categories (see chapter 7).

Table 1: Prevalence of medical conditions according to sex

BNF groupings of medical conditions	Male		Female	
	N = 27	%	N = 56	%
Cardiovascular	25	92.6	41	71.9
Gastro intestinal	13	41.1	33	57.9
Central nervous system	23	85.2	48	84.2
Respiratory system	9	33.3	17	29.8
Musculoskeletal	10	37	34	59.6
Endocrine system	6	22.2	17	29.8
Malignant & immunosuppression	1	3.7	6	10.5
Obstetrics, gynaecology, urinary tract	3	11.1	12	21.1
Pain				
Self report painful conditions	18	66.7	38	66.7
Prescribed pain relief	12	44.4	33	57.9
	Mean	SD	Mean	SD
Number of health categories per participant	3.33	1.38	3.68	1.62

Appendix 5 (b)

Reasons given for benzodiazepine use

With the exception of participants who gave “anxiety” (N = 6) as their reason for commencing benzodiazepine medication, “problem sleeping” was the primary reason given. Fifty five percent of participants were able to give a reason for their sleep difficulty. Thirty eight percent were unable to give a precipitant to their sleep problem. It is possible that a number of the 12 participants who reported “stress and worry” as the reason that they could not sleep, could have been experiencing an anxiety disorder such as generalised anxiety disorder (GAD).

Figure 1: Reason given for original benzodiazepine prescription

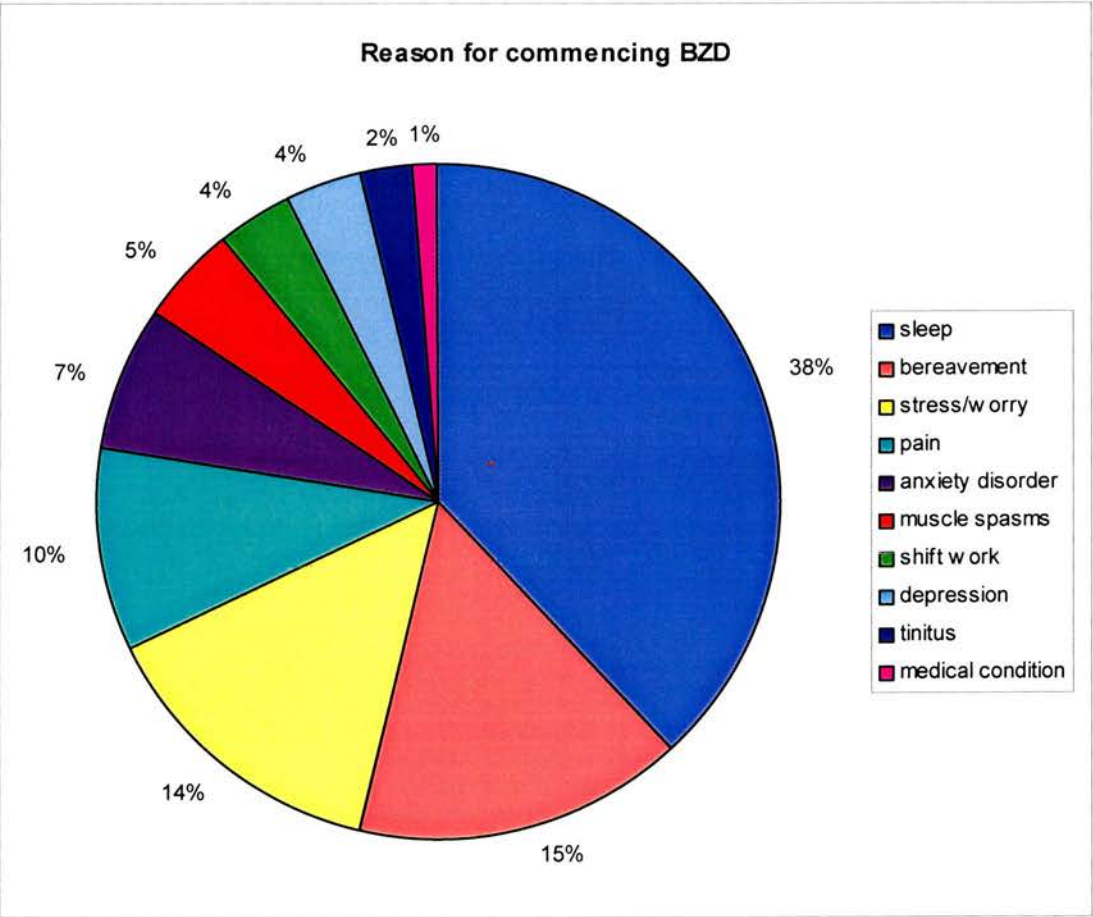
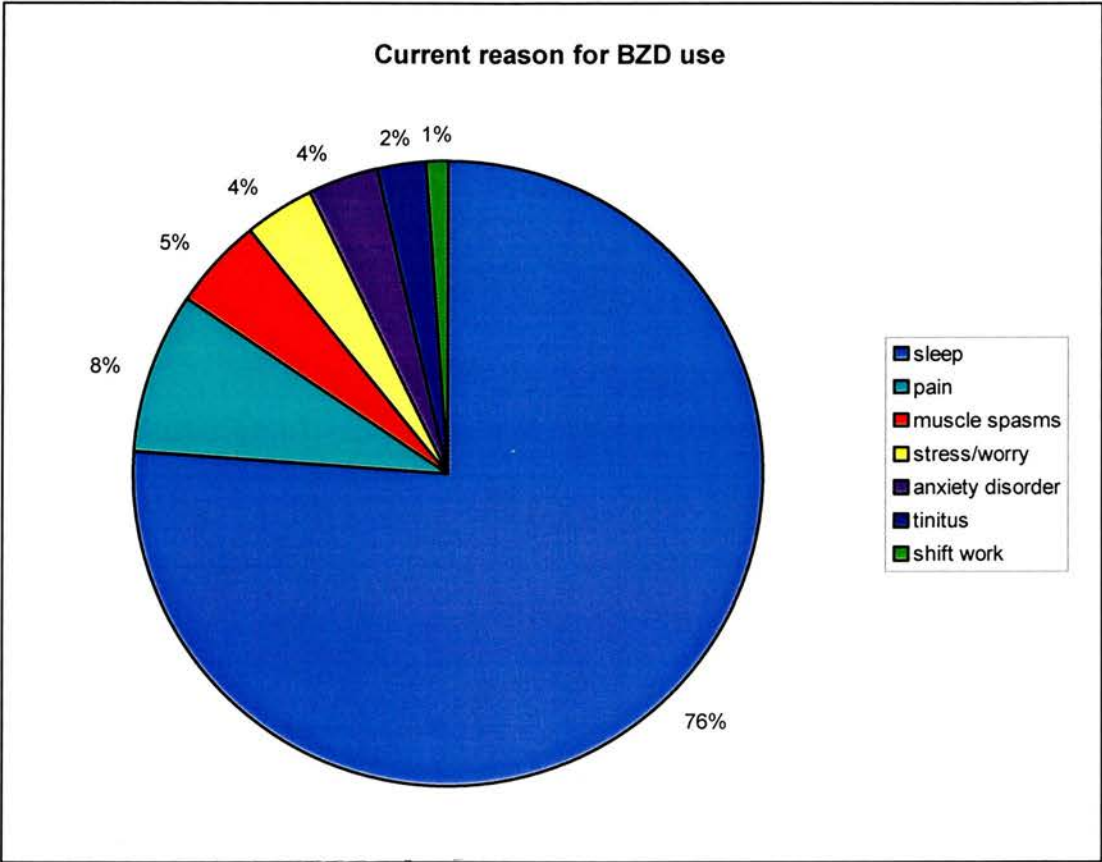


Figure 2 below gives the current reason for participants use of benzodiazepine medication. The majority of participants did not report a reason for their current sleep problem. Only three participants reported that their continued use of benzodiazepines was still for anxiety, these participants took their benzodiazepines during the daytime. The remaining 81 participants took their benzodiazepine at night.

Figure 2: Reason given for current use of benzodiazepine



The 13 participants who reported bereavement as their original reason for commencing benzodiazepines, reported sleep as their current reason for benzodiazepine use. The mean length of time since commencing a benzodiazepine, and therefore an indication of time since their bereavement was 10.9 years (mode = 14 years). Of the three participants who commenced benzodiazepine medication due to shift work, one participant (aged 56) continues to work shifts and had been using benzodiazepines for 3 years. The other two participants commenced benzodiazepines at the age of 52 and 61, they

continued to take them following their retirement and have now been taking them for 20 years each.

Twelve participants who commenced benzodiazepines because pain (N=6), muscle spasms (N=4) or tinnitus (N=2) was impairing their sleep, report the same reason for their current use of benzodiazepines.

After bereavement, stress and worry was the most commonly reported reason for sleep problems leading to commencement of benzodiazepine medication. Of the twelve participants who gave this reason, three said that they currently still had worries. These three participants had been taking their benzodiazepines for a mean duration of 3.6 years. The remaining nine participants said that the original stresses and worries had gone but that they still required benzodiazepines to sleep. This group of nine had been taking their benzodiazepines for an average of 10 years.

Appendix 5 (c)

Correlation matrix for SDS items

		out of control	worry miss a dose	worry use of	wish could stop	how difficult	total SDS
out of control	Correlation Coefficient	1.000					
	Sig. (2-tailed)	.					
	N	84					
worry miss a dose	Correlation Coefficient	.061	1.000				
	Sig. (2-tailed)	.583	.				
	N	84	84				
worry use of	Correlation Coefficient	.124	-.163	1.000			
	Sig. (2-tailed)	.263	.138	.			
	N	84	84	84			
wish could stop	Correlation Coefficient	.246*	-.070	.380**	1.000		
	Sig. (2-tailed)	.024	.529	.000	.		
	N	84	84	84	84		
how difficult	Correlation Coefficient	-.047	.444**	-.105	.059	1.000	
	Sig. (2-tailed)	.671	.000	.341	.596	.	
	N	84	84	84	84	84	
total SDS	Correlation Coefficient	.298**	.599**	.350**	.598**	.624**	1.000
	Sig. (2-tailed)	.006	.000	.001	.000	.000	.
	N	84	84	84	84	84	84

*. Correlation is significant at the .05 level (2-tailed).

**. Correlation is significant at the .01 level (2-tailed).

Note that in terms of the correlation of each item with the total SDS score, each item contributes to the total SDS score, this means that a proportion of the correlation coefficient is determined by its correlation with itself.

Appendix 5 (d)

The Pittsburgh Sleep Quality Index

Figure 3 below illustrates the mean score for each of the seven PSQI components. As one would expect questions regarding the “use of sleep medication” were the most highly endorsed. It would appear that “sleep latency” and “sleep efficiency” are also more problematic than other components.

Figure 3: Error bar chart to show mean scores on 7 components of PSQI & 95% CI

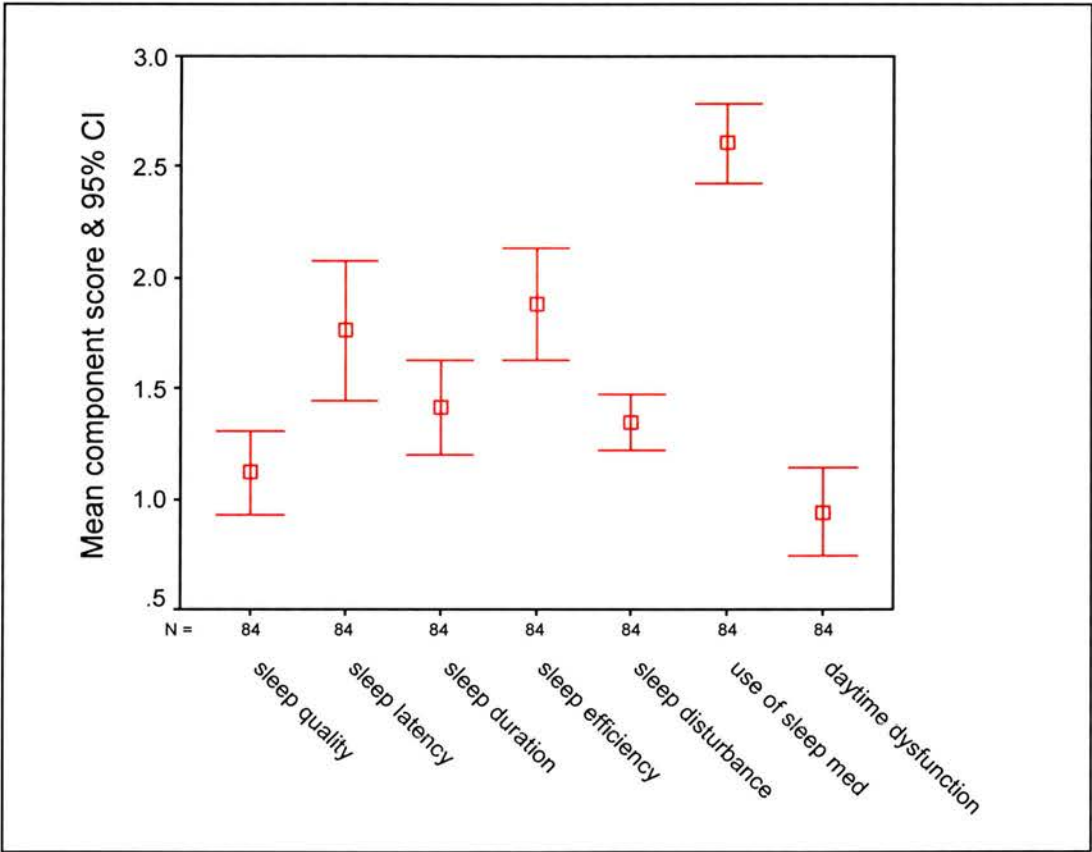


Figure 4: Sleep latency: distribution of number of minutes taken to fall asleep

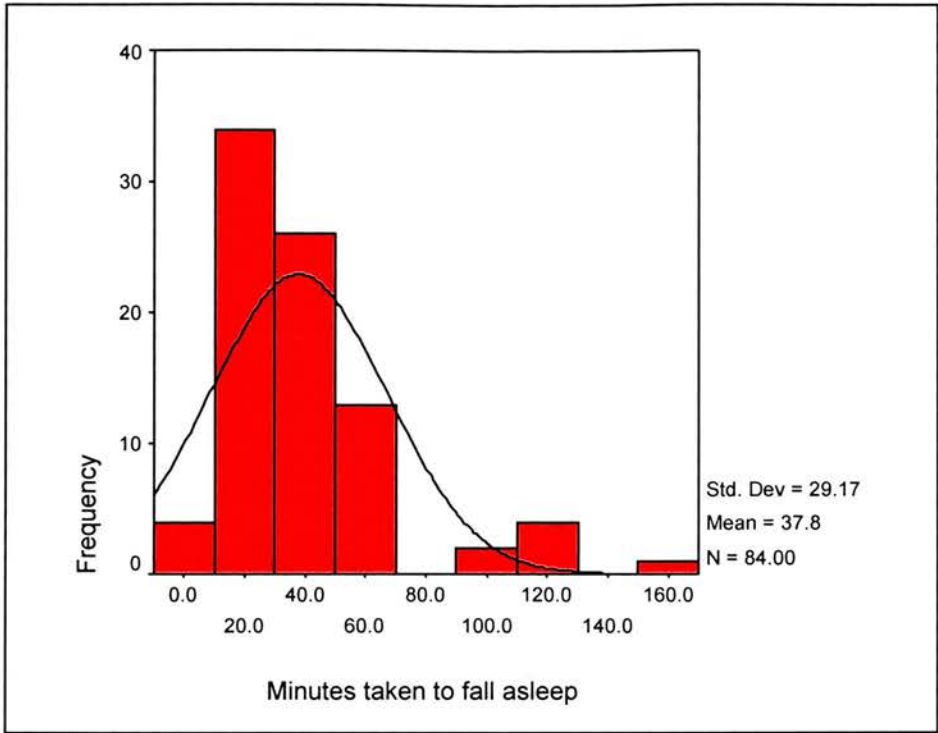


Figure 5: Sleep duration: total number of hours slept per night

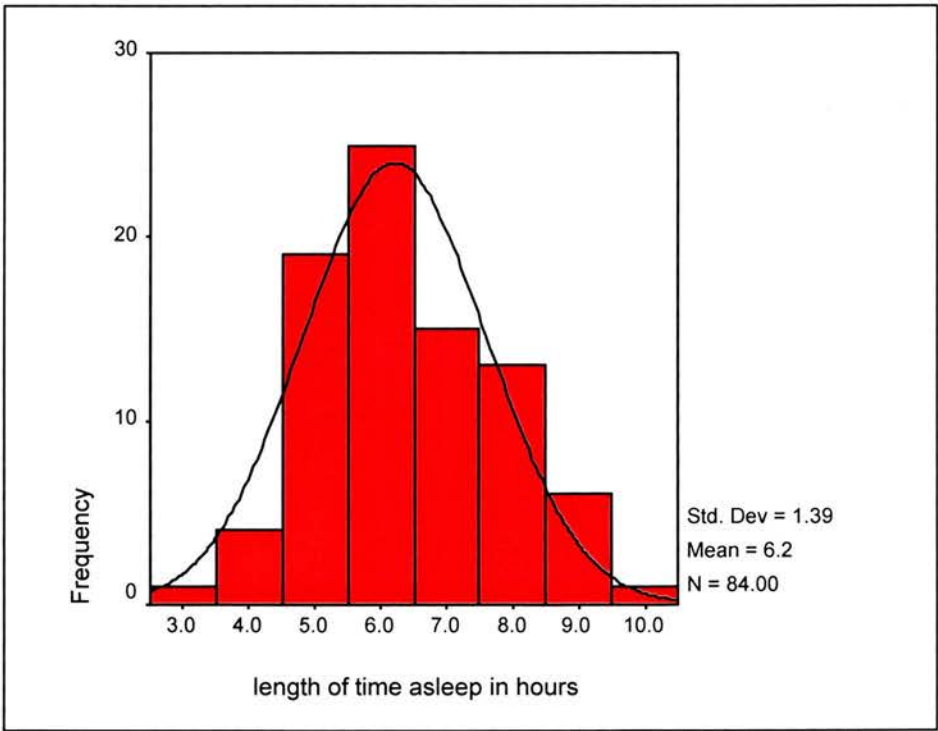


Table 2 below shows that a number of the BSI dimensions scores correlate with the PSQI component scores, demonstrating a relationship between increased sleep difficulty and higher levels of psychopathology. Daytime dysfunction demonstrates the strongest relationship with the BSI dimension scores. This is predictable on the basis that increased symptomatology is likely to lead to poorer general functioning, which could well be reflected in daytime dysfunction.

Sleep disturbance correlates significantly with all dimensions except interpersonal sensitivity. Interpersonal sensitivity is the dimension least associated with the sleep component scores, but this is not surprising because whilst this dimension is linked to anxiety and phobic anxiety, it is not a specific diagnosable condition.

Reduced sleep duration is associated with the “anxious” dimensions; anxiety, somatisation and phobic anxiety, suggesting that worry could be reducing total sleep time. Surprisingly however, sleep latency appears less of a problem for the anxious participants, instead it would appear to be those participants who scored more highly for depression who have more of a problem getting to sleep.

Table 2: Correlation matrix to show the relationship between BSI dimension scores and PSQI component scores

		Anxiety	Depression	Somatis- ation	Inter- personal sensitivit y	Phobic anxiety	Total BSI score
Subjective sleep quality	$r_s =$ $p =$.339 .002	.343 .001	.165 .134	.202 .066	.286 .008	.311 .004
Sleep latency	$r_s =$ $p =$.177 .107	.221 .043	.172 .117	.033 .763	.125 .257	.197 .073
Sleep duration	$r_s =$ $p =$.458 .000	.211 .054	.261 .016	.115 .300	.270 .013	.316 .003
Sleep efficiency	$r_s =$ $p =$.344 .001	.238 .029	.277 .011	.143 .194	.142 .197	.290 .007
Sleep disturbances	$r_s =$ $p =$.315 .004	.306 .005	.376 .000	.113 .305	.257 .018	.362 .001
Use of sleep medication	$r_s =$ $p =$.195 .076	.130 .239	.275 .011	.059 .594	.086 .439	.193 .079
Daytime dysfunction	$r_s =$ $p =$.344 .001	.259 .018	.472 .000	.345 .001	.237 .030	.458 .000

APPENDIX 6: SPSS OUTPUT

Appendix 6 (a)

ROC Curve

Appendix 6 (b)

General Linear Model: Three-Factor mixed ANOVA

General Linear Model: Two- Factor mixed ANOVA

Appendix 6 (c)

Regression Analysis for dependent variable SDS score

Logistic Regression for dependent variable BZD

Regression Analysis for dependent variable PSQI score

APPENDIX 6: SPSS OUTPUT

Appendix 6 (a)

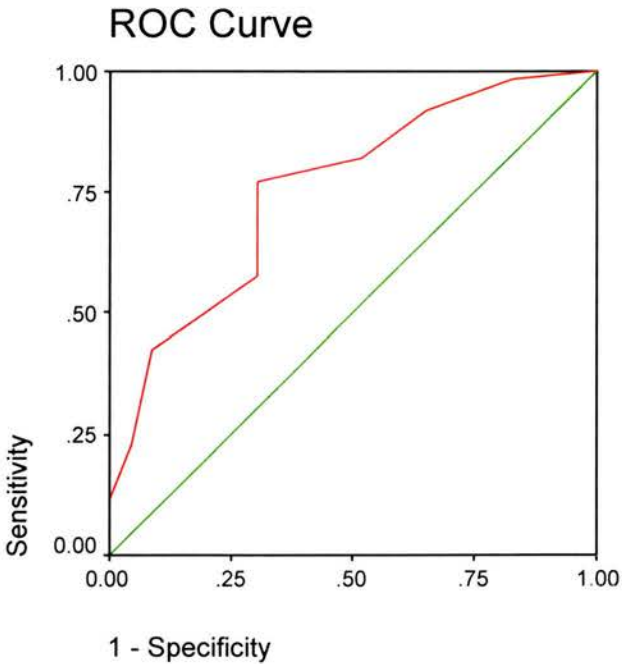
ROC Curve

Case Processing Summary

frequency of use	Valid N (listwise)
Positive ^a	61
Negative	23
Missing	1

Larger values of the test result variable(s) indicate stronger evidence for a positive actual state.

a. The positive actual state is use daily.



Diagonal segments are produced by ties.

Area Under the Curve

Test Result Variable(s): total SDS

Area	Std. Error ^a	Asymptotic Sig. ^b	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.754	.059	.000	.640	.869

The test result variable(s): total SDS has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

- a. Under the nonparametric assumption
- b. Null hypothesis: true area = 0.5

Coordinates of the Curve

Test Result Variable(s): total SDS

Positive if Greater Than or Equal To ^a	Sensitivity	1 - Specificity
-1.0000	1.000	1.000
.5000	.984	.826
1.5000	.918	.652
2.5000	.820	.522
3.5000	.770	.304
4.5000	.574	.304
5.5000	.426	.087
6.5000	.230	.043
7.5000	.115	.000
9.0000	.016	.000
11.0000	.000	.000

The test result variable(s): total SDS has at least one tie between the positive actual state group and the negative actual state group.

- a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

Appendix 6 (b)

General Linear Model: Three-Factor mixed ANOVA

Within-Subjects Factors

Measure: MEASURE_1

BSI	Dependent Variable
1	TRANPHO1
2	TRANDEP1
3	TRANINT1
4	TRANSOM1
5	TRANANX1

Between-Subjects Factors

		Value Label	N
SEX	1.00	male	27
	2.00	female	57
age group	1.00	over 60	68
	2.00	under 60	16

Descriptive Statistics

	SEX	age group	Mean	Std. Deviation	N
pho mean + 1 transformed	male	over 60	.1574	.3002	20
		under 60	.5452	.4854	7
		Total	.2580	.3876	27
	female	over 60	.2657	.3302	48
		under 60	.5902	.4360	9
		Total	.3169	.3646	57
	Total	over 60	.2338	.3233	68
		under 60	.5705	.4429	16
		Total	.2980	.3708	84
dep mean + 1 transformed	male	over 60	.3669	.3754	20
		under 60	.5549	.2835	7
		Total	.4156	.3586	27
	female	over 60	.4335	.3958	48
		under 60	.4608	.4226	9
		Total	.4378	.3964	57
	Total	over 60	.4139	.3883	68
		under 60	.5019	.3602	16
		Total	.4307	.3826	84
int mean +1 transformed	male	over 60	.2184	.2569	20
		under 60	.5433	.3823	7
		Total	.3026	.3210	27
	female	over 60	.3541	.3029	48
		under 60	.5673	.4735	9
		Total	.3877	.3394	57
	Total	over 60	.3142	.2949	68
		under 60	.5568	.4221	16
		Total	.3604	.3341	84
som mean +1 transform	male	over 60	.3971	.2667	20
		under 60	.6308	.3019	7
		Total	.4577	.2896	27
	female	over 60	.5193	.2576	48
		under 60	.5470	.3376	9
		Total	.5237	.2685	57
	Total	over 60	.4834	.2643	68
		under 60	.5837	.3148	16
		Total	.5025	.2754	84
anx mean +1 transform	male	over 60	.2128	.2952	20
		under 60	.7759	.2623	7
		Total	.3588	.3778	27
	female	over 60	.3228	.3515	48
		under 60	.5647	.5157	9
		Total	.3610	.3868	57
	Total	over 60	.2905	.3375	68
		under 60	.6571	.4255	16
		Total	.3603	.3817	84

Mauchly's Test of Sphericity^b

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon ^a		
					Greenhous e-Geisser	Huynh-Feldt	Lower-bound
BSI	.893	8.901	9	.447	.941	1.000	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b.

Design: Intercept+SEX+AGEGROUP+SEX * AGEGROUP

Within Subjects Design: BSI

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
BSI	Sphericity Assumed	.506	4	.127	2.269	.062
	Greenhouse-Geisser	.506	3.765	.135	2.269	.066
	Huynh-Feldt	.506	4.000	.127	2.269	.062
	Lower-bound	.506	1.000	.506	2.269	.136
BSI * SEX	Sphericity Assumed	.159	4	3.967E-02	.711	.585
	Greenhouse-Geisser	.159	3.765	4.215E-02	.711	.577
	Huynh-Feldt	.159	4.000	3.967E-02	.711	.585
	Lower-bound	.159	1.000	.159	.711	.402
BSI * AGEGROUP	Sphericity Assumed	.854	4	.213	3.825	.005
	Greenhouse-Geisser	.854	3.765	.227	3.825	.006
	Huynh-Feldt	.854	4.000	.213	3.825	.005
	Lower-bound	.854	1.000	.854	3.825	.054
BSI * SEX * AGEGROUP	Sphericity Assumed	.120	4	3.002E-02	.538	.708
	Greenhouse-Geisser	.120	3.765	3.189E-02	.538	.697
	Huynh-Feldt	.120	4.000	3.002E-02	.538	.708
	Lower-bound	.120	1.000	.120	.538	.465
Error(BSI)	Sphericity Assumed	17.855	320	5.580E-02		
	Greenhouse-Geisser	17.855	301.221	5.928E-02		
	Huynh-Feldt	17.855	320.000	5.580E-02		
	Lower-bound	17.855	80.000	.223		

Tests of Between-Subjects Effects

Measure: MEASURE_1

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	50.189	1	50.189	143.216	.000
SEX	3.053E-02	1	3.053E-02	.087	.769
AGEGROUP	3.948	1	3.948	11.266	.001
SEX * AGEGROUP	.458	1	.458	1.308	.256
Error	28.036	80	.350		

Pairwise Comparisons

Measure: MEASURE_1

(I) BSI	(J) BSI	Mean Difference (I-J)	Std. Error	Sig. ^a	95% Confidence Interval for Difference ^a	
					Lower Bound	Upper Bound
1	2	-6.439E-02	.051	1.000	-.212	8.327E-02
	3	-3.115E-02	.045	1.000	-.162	9.922E-02
	4	-.134*	.046	.045	-.266	-1.690E-03
	5	-7.943E-02	.047	.939	-.215	5.583E-02
2	1	6.439E-02	.051	1.000	-8.327E-02	.212
	3	3.324E-02	.045	1.000	-9.802E-02	.165
	4	-6.956E-02	.056	1.000	-.230	9.136E-02
	5	-1.504E-02	.048	1.000	-.155	.125
3	1	3.115E-02	.045	1.000	-9.922E-02	.162
	2	-3.324E-02	.045	1.000	-.165	9.802E-02
	4	-.103	.045	.256	-.233	2.767E-02
	5	-4.829E-02	.044	1.000	-.174	7.792E-02
4	1	.134*	.046	.045	1.690E-03	.266
	2	6.956E-02	.056	1.000	-9.136E-02	.230
	3	.103	.045	.256	-2.767E-02	.233
	5	5.451E-02	.047	1.000	-8.214E-02	.191
5	1	7.943E-02	.047	.939	-5.583E-02	.215
	2	1.504E-02	.048	1.000	-.125	.155
	3	4.829E-02	.044	1.000	-7.792E-02	.174
	4	-5.451E-02	.047	1.000	-.191	8.214E-02

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

General Linear Model: Two- Factor mixed ANOVA

Within-Subjects Factors

Measure: MEASURE_1

BSI	Dependent Variable
1	TRANPHO1
2	TRANDEP1
3	TRANINT1
4	TRANSOM1
5	TRANANX1

Between-Subjects Factors

	Value Label	N
SEX 1.00	male	20
2.00	female	48

Descriptive Statistics

	SEX	Mean	Std. Deviation	N
pho mean + 1 transformed	male	.1574	.3002	20
	female	.2657	.3302	48
	Total	.2338	.3233	68
dep mean + 1 transformed	male	.3669	.3754	20
	female	.4335	.3958	48
	Total	.4139	.3883	68
int mean +1 transformed	male	.2184	.2569	20
	female	.3541	.3029	48
	Total	.3142	.2949	68
som mean +1 transform	male	.3971	.2667	20
	female	.5193	.2576	48
	Total	.4834	.2643	68
anx mean +1 transform	male	.2128	.2952	20
	female	.3228	.3515	48
	Total	.2905	.3375	68

Mauchly's Test of Sphericity^a

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon ^a		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
BSI	.836	11.557	9	.240	.915	.990	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

- a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.
- b.
Design: Intercept+SEX
Within Subjects Design: BSI

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
BSI	Sphericity Assumed	2.318	4	.579	10.099	.000
	Greenhouse-Geisser	2.318	3.660	.633	10.099	.000
	Huynh-Feldt	2.318	3.960	.585	10.099	.000
	Lower-bound	2.318	1.000	2.318	10.099	.002
BSI * SEX	Sphericity Assumed	3.783E-02	4	9.457E-03	.165	.956
	Greenhouse-Geisser	3.783E-02	3.660	1.034E-02	.165	.946
	Huynh-Feldt	3.783E-02	3.960	9.553E-03	.165	.955
	Lower-bound	3.783E-02	1.000	3.783E-02	.165	.686
Error(BSI)	Sphericity Assumed	15.149	264	5.738E-02		
	Greenhouse-Geisser	15.149	241.547	6.272E-02		
	Huynh-Feldt	15.149	261.360	5.796E-02		
	Lower-bound	15.149	66.000	.230		

Tests of Between-Subjects Effects

Measure: MEASURE_1

Transformed Variable: Average

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	29.788	1	29.788	102.253	.000
SEX	.832	1	.832	2.856	.096
Error	19.227	66	.291		

Pairwise Comparisons

Measure: MEASURE_1

(I) BSI	(J) BSI	Mean Difference (I-J)	Std. Error	Sig. ^a	95% Confidence Interval for Difference ^a	
					Lower Bound	Upper Bound
1	2	-.189*	.048	.002	-.327	-5.008E-02
	3	-7.469E-02	.041	.752	-.195	4.531E-02
	4	-.247*	.044	.000	-.374	-.120
	5	-5.629E-02	.045	1.000	-.186	7.361E-02
2	1	.189*	.048	.002	5.008E-02	.327
	3	.114	.043	.101	-1.094E-02	.239
	4	-5.800E-02	.055	1.000	-.216	.100
	5	.132	.048	.070	-5.860E-03	.271
3	1	7.469E-02	.041	.752	-4.531E-02	.195
	2	-.114	.043	.101	-.239	1.094E-02
	4	-.172*	.041	.001	-.291	-5.345E-02
	5	1.840E-02	.040	1.000	-9.718E-02	.134
4	1	.247*	.044	.000	.120	.374
	2	5.800E-02	.055	1.000	-.100	.216
	3	.172*	.041	.001	5.345E-02	.291
	5	.190*	.046	.001	5.743E-02	.323
5	1	5.629E-02	.045	1.000	-7.361E-02	.186
	2	-.132	.048	.070	-.271	5.860E-03
	3	-1.840E-02	.040	1.000	-.134	9.718E-02
	4	-.190*	.046	.001	-.323	-5.743E-02

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

a. Adjustment for multiple comparisons: Bonferroni.

Appendix 6 (c)

Regression Analysis for dependent variable SDS score

Variables Entered/Removed^d

Model	Variables Entered	Variables Removed	Method
1	LNANX		Stepwise (Criteria: Probabilit y-of-F-to-e nter <= .050, Probabilit y-of-F-to-r emove >= .100).
2			Stepwise (Criteria: Probabilit y-of-F-to-e nter <= .050, Probabilit y-of-F-to-r emove >= .100).

a. Dependent Variable: total SDS

Model Summary^f

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.417 ^a	.174	.164	2.1507
2	.469 ^b	.220	.201	2.1025

a. Predictors: (Constant), LNANX

b. Predictors: (Constant), LNANX, LNSOM

c. Dependent Variable: total SDS

ANOVA^f

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	79.868	1	79.868	17.268	.000 ^a
	Residual	379.275	82	4.625		
	Total	459.143	83			
2	Regression	101.070	2	50.535	11.432	.000 ^b
	Residual	358.073	81	4.421		
	Total	459.143	83			

a. Predictors: (Constant), LNANX

b. Predictors: (Constant), LNANX, LNSOM

c. Dependent Variable: total SDS

Coefficients^a

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	3.159	.359		8.812	.000
	LNANX	1.073	.258	.417	4.155	.000
2	(Constant)	1.989	.639		3.112	.003
	LNANX	.766	.289	.298	2.650	.010
	LNSOM	.919	.420	.246	2.190	.031

a. Dependent Variable: total SDS

Excluded Variables^c

Model		Beta In	t	Sig.	Partial Correlation	Collinearity Statistics
						Tolerance
1	LNINTER	.086 ^a	.706	.482	.078	.689
	LNSOM	.246 ^a	2.190	.031	.236	.764
	LNDEP	.098 ^a	.762	.449	.084	.615
	LNPHOB	.027 ^a	.218	.828	.024	.676
2	LNINTER	.019 ^b	.158	.875	.018	.642
	LNDEP	.057 ^b	.452	.652	.050	.601
	LNPHOB	-.057 ^b	-.451	.654	-.050	.616

a. Predictors in the Model: (Constant), LNANX

b. Predictors in the Model: (Constant), LNANX, LNSOM

c. Dependent Variable: total SDS

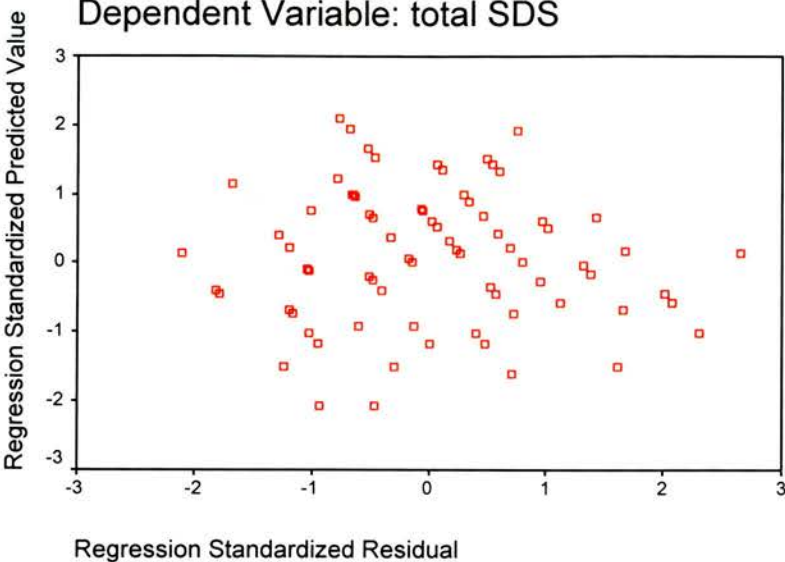
Residuals Statistics^a

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	1.9890	6.6109	4.2857	1.1035	84
Residual	-4.4310	5.5690	-8.78E-16	2.0770	84
Std. Predicted Value	-2.081	2.107	.000	1.000	84
Std. Residual	-2.107	2.649	.000	.988	84

a. Dependent Variable: total SDS

Scatterplot

Dependent Variable: total SDS



Logistic Regression for dependent variable BZD

Case Processing Summary

Unweighted Cases ^a		N	Percent
Selected Cases	Included in Analysis	84	100.0
	Missing Cases	0	.0
	Total	84	100.0
Unselected Cases		0	.0
Total		84	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
problem	0
no problem	1

Block 0: Beginning Block

Classification Table^{a,b}

Observed			Predicted		
			cut off 4		Percentage Correct
			problem	no problem	
Step 0	cut off 4	problem	54	0	100.0
		no problem	30	0	.0
Overall Percentage					64.3

- a. Constant is included in the model.
b. The cut value is .500

Variables in the Equation

	B	S.E.	Wald	df	Sig.	Exp(B)
Step 0 Constant	-.588	.228	6.662	1	.010	.556

Variables not in the Equation

	Score	df	Sig.
Step 0 Variables	ANXMEAN	14.924	1
	INTMEAN	5.147	1
	SOMEAM	11.050	1
	DEPMEAN	11.204	1
	PHOBMEAN	6.639	1
Overall Statistics		23.085	5

Block 1: Method = Backward Stepwise (Conditional)

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	32.350	5	.000
	Block	32.350	5	.000
	Model	32.350	5	.000
Step 2 ^a	Step	-.004	1	.951
	Block	32.346	4	.000
	Model	32.346	4	.000
Step 3 ^a	Step	-2.557	1	.110
	Block	29.789	3	.000
	Model	29.789	3	.000
Step 4 ^a	Step	-2.450	1	.118
	Block	27.339	2	.000
	Model	27.339	2	.000

a. A negative Chi-squares value indicates that the Chi-squares value has decreased from the previous step.

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	77.146	.320	.439
2	77.149	.320	.439
3	79.706	.299	.410
4	82.156	.278	.381

Classification Table^a

Observed			Predicted		
			cut off 4		Percentage Correct
			problem	no problem	
Step 1	cut off 4	problem	43	11	79.6
		no problem	9	21	70.0
	Overall Percentage				76.2
Step 2	cut off 4	problem	43	11	79.6
		no problem	9	21	70.0
	Overall Percentage				76.2
Step 3	cut off 4	problem	40	14	74.1
		no problem	11	19	63.3
	Overall Percentage				70.2
Step 4	cut off 4	problem	39	15	72.2
		no problem	9	21	70.0
	Overall Percentage				71.4

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1	ANXMEAN	-2.619	1.040	6.343	1	.012	.073
	INTMEAN	1.348	.886	2.316	1	.128	3.851
	SOMEAM	-1.193	.692	2.969	1	.085	.303
	DEPMEAN	-1.304	.837	2.428	1	.119	.271
	PHOBMEAN	.046	.751	.004	1	.951	1.048
	Constant	1.145	.518	4.878	1	.027	3.143
Step 2	ANXMEAN	-2.615	1.037	6.354	1	.012	.073
	INTMEAN	1.359	.870	2.437	1	.119	3.891
	SOMEAM	-1.186	.683	3.020	1	.082	.305
	DEPMEAN	-1.290	.801	2.593	1	.107	.275
	Constant	1.143	.518	4.881	1	.027	3.137
Step 3	ANXMEAN	-2.145	.936	5.253	1	.022	.117
	SOMEAM	-1.007	.662	2.318	1	.128	.365
	DEPMEAN	-.948	.692	1.879	1	.170	.387
	Constant	1.264	.513	6.073	1	.014	3.541
Step 4	ANXMEAN	-2.373	.916	6.713	1	.010	.093
	DEPMEAN	-1.061	.688	2.380	1	.123	.346
	Constant	.762	.379	4.030	1	.045	2.142

a. Variable(s) entered on step 1: ANXMEAN, INTMEAN, SOMEAM, DEPMEAN, PHOBMEAN.

Model if Term Removed^a

Variable		Model Log Likelihood	Change in -2 Log Likelihood	df	Sig. of the Change
Step 1	ANXMEAN	-43.278	9.411	1	.002
	INTMEAN	-39.804	2.463	1	.117
	SOMEAM	-40.156	3.167	1	.075
	DEPMEAN	-41.195	5.244	1	.022
	PHOBMEAN	-38.575	.004	1	.951
Step 2	ANXMEAN	-43.318	9.488	1	.002
	INTMEAN	-39.879	2.609	1	.106
	SOMEAM	-40.184	3.219	1	.073
	DEPMEAN	-41.259	5.368	1	.021
Step 3	ANXMEAN	-43.544	7.382	1	.007
	SOMEAM	-41.082	2.459	1	.117
	DEPMEAN	-41.517	3.327	1	.068
Step 4	ANXMEAN	-46.425	10.695	1	.001
	DEPMEAN	-43.093	4.030	1	.045

a. Based on conditional parameter estimates

Variables not in the Equation

			Score	df	Sig.
Step 2 ^a	Variables	PHOBMEAN	.004	1	.951
	Overall Statistics		.004	1	.951
Step 3 ^b	Variables	INTMEAN	2.549	1	.110
		PHOBMEAN	.143	1	.705
	Overall Statistics		2.552	2	.279
Step 4 ^c	Variables	INTMEAN	1.815	1	.178
		SOMEAM	2.466	1	.116
		PHOBMEAN	.006	1	.937
	Overall Statistics		4.973	3	.174

- Variable(s) removed on step 2: PHOBMEAN.
- Variable(s) removed on step 3: INTMEAN.
- Variable(s) removed on step 4: SOMEAM.

Regression Analysis for dependent variable PSQI score

Descriptive Statistics

	Mean	Std. Deviation	N
global score	11.0714	4.0592	84
LNANX	1.0497	.9141	84
LNINTER	.8752	.7153	84
LNSOM	1.6244	.6292	84
LNDEP	1.2310	.8221	84
LNPHOB	.7824	.8689	84

Correlations

		global score	LNANX	LNINTER	LNSOM	LNDEP	LNPHOB
Pearson Correlation	global score	1.000	.502	.232	.443	.408	.335
	LNANX	.502	1.000	.558	.486	.620	.569
	LNINTER	.232	.558	1.000	.460	.598	.579
	LNSOM	.443	.486	.460	1.000	.405	.492
	LNDEP	.408	.620	.598	.405	1.000	.601
	LNPHOB	.335	.569	.579	.492	.601	1.000
Sig. (1-tailed)	global score	.	.000	.017	.000	.000	.001
	LNANX	.000	.	.000	.000	.000	.000
	LNINTER	.017	.000	.	.000	.000	.000
	LNSOM	.000	.000	.000	.	.000	.000
	LNDEP	.000	.000	.000	.000	.	.000
	LNPHOB	.001	.000	.000	.000	.000	.
N	global score	84	84	84	84	84	84
	LNANX	84	84	84	84	84	84
	LNINTER	84	84	84	84	84	84
	LNSOM	84	84	84	84	84	84
	LNDEP	84	84	84	84	84	84
	LNPHOB	84	84	84	84	84	84

Variables Entered/Removed^a

Model	Variables Entered	Variables Removed	Method
1	LNANX		Stepwise (Criteria: Probabilit y-of-F-to-e nter <= .050, Probabilit y-of-F-to-r emove >= .100).
2	LNSOM		Stepwise (Criteria: Probabilit y-of-F-to-e nter <= .050, Probabilit y-of-F-to-r emove >= .100).

a. Dependent Variable: global score

Model Summary^f

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.502 ^a	.252	.243	3.5312
2	.552 ^b	.304	.287	3.4271

a. Predictors: (Constant), LNaNX

b. Predictors: (Constant), LNaNX, LNSOM

c. Dependent Variable: global score

ANOVA^f

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	345.102	1	345.102	27.676	.000 ^a
	Residual	1022.470	82	12.469		
	Total	1367.571	83			
2	Regression	416.203	2	208.102	17.718	.000 ^b
	Residual	951.368	81	11.745		
	Total	1367.571	83			

a. Predictors: (Constant), LNaNX

b. Predictors: (Constant), LNaNX, LNSOM

c. Dependent Variable: global score

Coefficients^a

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	8.730	.589		14.830	.000
	LNaNX	2.231	.424	.502	5.261	.000
2	(Constant)	6.587	1.042		6.323	.000
	LNaNX	1.668	.471	.376	3.542	.001
	LNSOM	1.683	.684	.261	2.460	.016

a. Dependent Variable: global score

Excluded Variables^f

Model		Beta In	t	Sig.	Partial Correlation	Collinearity Statistics
						Tolerance
1	LNINTER	-.069 ^a	-.598	.551	-.066	.689
	LNSOM	.261 ^a	2.460	.016	.264	.764
	LNDEP	.157 ^a	1.294	.200	.142	.615
	LNPJOB	.073 ^a	.623	.535	.069	.676
2	LNINTER	-.151 ^b	-1.312	.193	-.145	.642
	LNDEP	.115 ^b	.965	.337	.107	.601
	LNPJOB	-.012 ^b	-.097	.923	-.011	.616

a. Predictors in the Model: (Constant), LNaNX

b. Predictors in the Model: (Constant), LNaNX, LNSOM

c. Dependent Variable: global score

Coefficient Correlations^a

Model			LNANX	LNSOM
1	Correlations	LNANX	1.000	
	Covariances	LNANX	.180	
2	Correlations	LNANX	1.000	-.486
		LNSOM	-.486	1.000
	Covariances	LNANX	.222	-.157
		LNSOM	-.157	.468

a. Dependent Variable: global score

Residuals Statistics^a

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	6.5869	15.7697	11.0714	2.2393	84
Residual	-7.4360	5.9238	-1.82E-15	3.3856	84
Std. Predicted Value	-2.003	2.098	.000	1.000	84
Std. Residual	-2.170	1.729	.000	.988	84

a. Dependent Variable: global score

Scatterplot

Dependent Variable: global score

